PROCUREMENT AND ALLOCATION OF HUMAN ORGANS FOR TRANSPLANTATION

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
INVESTIGATIONS AND OVERSIGHT

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

NINETY-EIGHTH CONGRESS

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PROCUREMENT AND ALLOCATION OF HUMAN ORGANS FOR TRANSPORTATION

MONDAY, NOVEMBER 7, 1983

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:17 a.m., in room 2318, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. Gore. The subcommittee will come to order. Good morning to everyone. I would like to welcome our witnesses and guests.

This week we continue our investigation of issues related to human organ transplantation by focusing today on transplantation of nonimmigrant aliens. Wednesday we will turn our attention to the commercial sale of organs.

Organ transplantation represents for some the only chance for life, and for others the only chance for a quality life. When the subcommittee began its inquiry some 10 months ago, we sought to understand why, in a Nation with 20,000 potential donors each year, there is a shortage of transplantable organs. Our investigation took us through the labyrinth of transplantation and brought us into contact with children and adults needing transplants, and brought us into contact as well with some modern-day heroes—the transplant coordinators and the transplant surgeons.

Last month, as a result of our efforts, I introduced, along with Joe Skeen, our ranking minority member, and Henry Waxman, chairman of the Health Subcommittee, the National Organ Transplant Act, H.R. 4080. The act is designed to enhance our Nation's ability to harvest organs, and I am hopeful the House will act on this legislation before its November adjournment.

As we set about to meet the growing demand for transplantable organs, we all need to recognize the obligation owed to potential donors to assure them that their organs are equitably allocated, and the equal obligation owed to potential recipients to assure them that no one is prejudiced or treated unfairly in the process of organ distribution. We will look directly at these obligations today, and the specific issues we focus on—transplantation for nonimmigrant aliens—is as emotional as it is complex.

From the very beginning, America has been a land to welcome those in need. During the centuries, we have sheltered those fleeing religious persecution, those seeking economic opportunity, and those seeking political freedom. Today, as a tribute to modern

American medicine, people are coming to this country for medical care, and nowhere is this trend more evident than in the field of organ transplantation. Indeed, we will hear from some of those people today whose very reputations have attracted this international following.

And herein lies the seeds of our dilemma: How does America, in the face of scarcity of transplantable organs, maintain its tradition of making first-class medical care available for its own citizens while continuing to offer the same standard of care to nonimmigrant aliens?

Recently, reports in the media have suggested that wealthy nonimmigrant aliens have been given priority for kidneys in some cases over Americans. If those reports are true, then we are not fulfilling all of our obligations. Let me share with you some facts and preliminary conclusions from this investigation:

Sixty-five thousand people are on dialysis for end-stage renal disease, at least 6,500 of whom are on waiting lists for transplants.

Incidentally, we will find in today's hearings that there are a large number, evidently, of people on dialysis who should be on waiting lists for transplants but are not.

Second, the shortage of transplantable kidneys plays a role in keeping people on the waiting list.

Third, nonimmigrant aliens are receiving kidney transplants in the United States, and while the number according to a survey conducted for the subcommittee by the Health Care Finance Administration, is relatively small, ranging from 3 to 7 percent of the total cadaveric transplants during the last 3 years, the number in certain limited geographical areas is substantially higher.

Fourth, because of the system of organ allocation, some nonimmigrant aliens are receiving kidneys that could be used in Americans.

Fifth, hospitals and some surgeons generally receive more money for transplanting a nonmedicare recipient, such as a nonimmigrant alien, than for medicare patients.

Now, while these facts are entirely clear—and we will be exploring them in the hearing—what is not clear at all is the extent the transplantation of nonimmigrant aliens presents a nationwide problem. It is not clear the extent to which it affects the end stage renal disease program, and the extent to which finances and other factors provide incentives to transplant nonimmigrant aliens.

Today we will hear how nonimmigrant aliens get to the United States transplant centers, how they get organs, and we will probe the scientific, clinical, ethical, and financial factors that go into organ allocation decisions.

In our inquiry, we will seek answers to three major questions: First, what is the role of science in decisions concerning allocation of human organs, primarily kidneys in this hearing; second, to what extent are nonresident aliens being transplanted in U.S. facilities and are they receiving organs that are more appropriately, from a scientific standpoint, transplanted in Americans; and third, to what extent does the practice of transplanting foreign nationals have a potential to undermine the voluntary system of organ donation.

I look forward to a difficult and complex, yet significant, hearing, which I anticipate and hope will shed much light on these questions.

Before going to our witnesses, I want to call on my friend and colleague, the ranking minority member, Joe Skeen.

Mr. SKEEN. Thank you very much, Mr. Chairman.

I'm not going to take a lot of our time this morning with an opening statement. I think it's extremely important that we get into the meat of this hearing. However, I would like to make this observation, that at the very beginning, when we contemplated the drafting of this legislation, and in promoting it with Members of Congress, and following it through its course, one of the most nagging and constant aspects of this particular question has been the monetary influence on the program itself. I think it is extremely important that we have taken up particularly the question of nonresident aliens and what has been the effect on allocations, if any, in the system as it exists today, in the allocation of transplantable organs.

So, I look forward to this testimony and I want to commend the chairman for the hearings. I think it's an important aspect and I hope we can illuminate this thing fully. I appreciate the witnesses being here this morning and giving us the advantage of their testimony and their view, particularly those who are practitioners in this particular field.

Thank you very much, Mr. Chairman.

Mr. GORE. Thank you very much, Mr. Skeen.

Let me say at the outset that on some occasions, as an investigative subcommittee, we swear all witnesses in during some hearings. I trust that none of our witnesses today will get the implication in any way, shape or form that we don't think your testimony would be perfectly forthright without that. But some hearings, by their investigative nature it seems to me, make it a little more appropriate that we get sworn testimony. Many subcommittees on Capitol Hill do that.

Do any of you have objections to being sworn? If you would raise your right hand and repeat after me—you may remain seated, Ms. Lindsay—if the other three of you would please stand.

Do you solemnly swear the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses answer affirmatively.]

Mr. GORE. Thank you very much.

Let me introduce all four of you. Dr. Peter Ivanovich, who is with the Northwestern University Medical School in Chicago; Ernest Bauer, chairperson of the Patient Action Committee with ESRD Network 23 in Washington; Miss Barbara Lindsay of College Park, Md.; and Professor Warren Reich, director of the Division of Health and Humanities, Georgetown University School of Medicine in Washington.

Dr. Ivanovich, we would like to begin with you, and let me explain to all of our witnesses that we will take the full panel's statements before going to questions for the entire panel. If you care to summarize any portions of your statement, please feel free to do so because, without objection, we will put the entire text of your prepared statements in the record in full.

We would like to begin, Dr. Ivanovich, with you. We want to welcome you here and thank you for your willingness to help us in this endeavor.

STATEMENTS OF PETER IVANOVICH, M.D., DEPARTMENT OF MEDICINE, NORTHWESTERN UNIVERSITY; ERNEST T. BAUER, CHAIRPERSON, PATIENT ACTION COMMITTEE, END STAGE RENAL DISEASE NETWORK 23; BARBARA LINDSAY, MEMBER, ESRD NETWORK 23; AND WARREN REICH, PROFESSOR OF BIOETHICS, DIRECTOR, DIVISION OF HEALTH AND HUMANITIES, DEPARTMENT OF COMMUNITY AND FAMILY MEDICINE, GEORGETOWN UNIVERSITY

Dr. IVANOVICH. Thank you, Chairman Gore, members of the committee, colleagues, ladies, and gentlemen. It is an honor and privilege to appear before this committee. I hope that my testimony will be informative and of some practical value to you.

My name is Peter Ivanovich. I am a nephrologist on the part-time staff of the Chicago Veterans Administration Lakeside Medical Center, where I am chief of hemodialysis. The hospital is academically affiliated with Northwestern University Medical School. There I am a professor of medicine. Northwestern has adult and pediatric transplantation facilities and I have been privileged to participate in both.

There is a priority system for transplantation based first on sensitization, then on histocompatability and other clinical factors. The Illinois Association of Transplant Surgeons recognizes nine categories of patient priority. The nonresident alien falls within the ninth.

How did the cooperative program with the Saudis come about? In February 1981, a delegation of two physicians from Saudi Arabia came to the United States and visited several transplant centers to see if cadaveric kidney transplantation could be performed on their renal failure patients. Uni-Med International Corp. became involved through its president, Mr. Richard Spencer, who had had prior dealings with the Saudis and knew one of these physicians. He submitted a proposal to the Saudi Ministry of Health, offering the services of his company, with me as a consultant, to organize a program to assist in the placement of Saudi patients.

He and I visited Saudi Arabia in July 1981 and met with members of a General Medical Committee of the Ministry of Health. The physicians were interested in the Uni-Med proposal but stated they were unable to provide histocompatability and lymphocytotoxic screening on each patient. We believed we could circumvent that problem by making arrangements with the typing laboratory in this country, to have the blood flown in from Riyadh. We did emphasize that the number of qualified centers should be increased, as necessary, so that at no center would Saudi patients represent more than 5 to 10 percent of those transplantable.

They readily accepted Uni-Med's proposal to monitor all charges from participating institutions, so that only standard fees would be submitted. Although I was interested in the concept of an organized program, I had reservations, principally because I feared communications between the centers in Saudi Arabia and the United States would be inadequate and I would be left in the middle. However, the contract was signed.

While we were in the process of setting up the mechanism of the program, some of my fears were recognized and I realized that it would become a demanding task to monitor transfers of patients from one country to another. The Saudis had already begun sending patients with minimal information. Unfortunately, some were unsuitable; hence, both the Saudi General Medical Committee and U.S. transplant centers decided to call a halt until our program became operational.

I set up the administrative paperwork for data collection and was able to make arrangements with the typing laboratory at the New York Blood Center to analyze blood samples to be sent in advance from Saudi Arabia. I am happy to say that the program is now functioning well. Furthermore, all administrative and medical details have been transferred to an efficient and organized Saudi Medical Health Office in Washington.

Over a 2-year period, 92 patients have been entered into the cooperative program. Seventeen never traveled to this country primarily because of high lymphocytotoxic titers. Seventy-five have been transplanted at 18 centers. In 1982, 21 patients were transplanted. Up until September 1982, 19 were transplanted. This represents but a fraction of the total number of transplants performed in this country. To the best of my knowledge, this is the largest and only organized program of such service to foreign nationals.

We are pleased with the project. We believe that medicine, like music, should recognize no cultural or national barriers. We can provide a service which, in turn, allows institutions in this country to profit from experience gained from a select group of patients, some with conditions physicians do not normally encounter. In addition, the fees that they help pay defray the costs normally borne by those hospitals and third party payers.

What is important is that the people are coming to us. There was a time when American physicians and patients traveled to European capitals for training and care because they were considered the meccas of medicine. Now trainees and patients from all over the world come to us, as some of my fellow witnesses will probably testify.

The Saudis, for example, send their patients not only for kidney transplantation, but also for other specialized surgical services. They believe that we can provide for their patients and we have demonstrated that we can. I believe we should continue to do so as long as it does not prejudice the care of our own patients.

To the best of my knowledge, no American has been denied the opportunity for kidney transplantation as a result of this effort. The service is intentially designed not to strain the facilities of the institutions. We believe that this international medical endeavor will enhance relationships between the two countries. It has already developed understanding and concern for people of significant cultural differences.

All of us who have participated have dedicated a great proportion of our time to this effort. We are convinced it has been worthwhile. I regard it as one of my most significant contributions.

Thank you for your patience.

[The prepared statement of Dr. Ivanovich follows:]

Testimony Presented Before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology of the House of Representatives

Rayburn House Office Building

November 7, 1983

by
Peter Ivanovich, M.D.

BIOGRAPHICAL SKETCH

Peter Ivanovich, M.D.

Born Gig Harbor, Washington, November 9, 1928. Graduated from Seattle University 1951 and St. Louis University School of Medicine 1955.

Internship and residency in internal medicine in San Francisco interrupted by 3½-year term as Captain in the United States Army Medical Corps in Germany. Resigned commission to spend several months in training in internal medicine at the Medical Faculty of Zagreb, Yugoslavia, country of parents.

In 1962, after residency training in San Francisco, pursued more than 4 years postdoctoral fellowship in endocrinology, calcium disorders and nephrology in Seattle.

In 1966 became Director of Chronic Dialysis and Research at Sacred Heart Hospital, Spokane, directing the first of two federally funded programs for home hemodialysis. Subsequently was consultant to the Kidney Disease Program of the United States Public Health Service, administering and monitoring similar grants at other institutions.

From 1968 through 1974 was first Director and Chief Executive Officer of Life Instrumentation Section and later Medical Director of the International Division of American Hospital Supply Corporation.

In 1971 became Chief, Hemodialysis Unit, Veterans Administration Lakeside Medical Center and Director, Organ Preservation Laboratory, Children's Memorial Hospital, Chicago, with the academic title of Assistant Professor of Medicine at Northwestern University Medical School. Promoted to Associate Professor of Medicine in 1975 and to Professor of Medicine in 1979.

Has been a member Advisory Committee Artificial Kidney Chronic Uremia Program of National Institutes of Arthritis, Metabolism, Digestive and Renal Diseases, Project Advisor Bureau of Medical Devices Food and Drug Administration, Consultant and Site Visitor for the Department of Medicine Veterans Administration Central Office, presently member of committees and active in national and international societies of Artificial Organs, Dialysis and Tranplantation, member editorial advisory boards in both English and German language medical/scientific journals.

Research and clinical activities in nephrology, dialysis and transplantation have led to the publication of 62 articles and more than 80 invitations from national and international organizations to assume visiting professorships or participate in scientific meetings.

Recipient of several awards from societies and/or foreign governments in Japan East Germany and the People's Republic of China.

The testimony I am to give is in response to Congressman Albert Gore's request of October 25, 1983. My name is Peter Ivanovich. I am a PART-TIME nephrologist at the Chicago Veterans Administration Lakeside Medical Center and have an academic affiliation with the Department of Medicine of Northwestern University Medical School. My training is in internal medicine, nephrology including dialysis and transplantation. I have been active in my specialty for 18 years. It is an honor for me to testify before this Committee and I trust that my testimony will be of some value to its Chairman and members.

The following are answers to questions concerning kidney transplantation raised in Congressman Gore's letter.

The priority system Northwestern University's two transplant facilities uses for the allocation of human kidneys is as follows: Those patients with greater than 50% sensitization are given the higest priority. This priority is then followed by histocompatability and clinical factors in patient selection.

The policy accorded non-resident aliens is that of the Illinois Association of Transplant Surgeons in which there are nine categories of priority. The ninth category is non-resident aliens. In 1981 there were 42 kidney transplants performed; in 1982 43 and thus far in 1983 there have been 33 kidney transplants performed. During the past three years one non-resident alien was transplanted.

Non-resident aliens in the past have come to Northwestern University by physician referral from physicians in other countries. A Chicago-based foreign diplomat referred himself for transplantation. Northwestern University has no agreement with a foreign government for transplantation.

Northwestern University does not charge a differential rate to receive additional payment from or on behalf of non-resident alien or other non-Medicare patients for organ acquisition, dialysis, hospitalization or transplant surgery. We are not aware of any foreign natinal who has been placed out of turn at the head of any transplant priority list.

We do not believe there should be a uniform established policy on transplantation of non-resident aliens. It is our belief that this is a decision which should be made by the physicians and administration of each specific institution.

Details of allocation of organs for transplantation may be obtained from such organizations as Scandia Transplant and Euro Transplant whose member institutions in various Scandinavian and other European countries share organs for transplantation. On a first-hand basis I am aware of the allocation of organs for transplantation in the German Democratic Republic since in 1978 I referred a hemodialysis patient friend from an Eastern European country to the German Democratic Republic for transplantation. That person a physician was hemodialyzed in the German Democratic Republic for four years before ultimately receiving a successful cadaveric kidney transplant. She has subsequently returned to her country and is re-establishing her position as a microbiologist in a medical facility.

Kidneys are sent out of the United States generally when they are unacceptable to U.S. institutions. Northwestern University's organ preservation laboratory sent three kidneys out of the United States to Turkey. One was from an elderly donor; the other two were kidneys which had multiple cysts. In each instance no one contacted in the United States wished to use these kidneys for transplantation.

In February 1981 a delegation of two physicians from Saudi Arabia traveled to this country to determine whether cadaveric kidney transplantation could be performed on Saudi renal failure patients at some U.S. centers. I was told by these physicians that the office of our Embassy in Riyadh had arranged for them to meet with a physician of the National Institutes of Arthritis, Metabolic, Digestive and Renal Diseases to assist in arranging an itinerary of several transplant centers in the United States. Amongst other U.S. centers active in cadaveric kidney transplantation the two physicians visited Northwestern University.

During their visit in February '81 they explained that their country's population experienced a relatively high incidence of chronic renal failure. These patients were dialyzed at numerous centers in Saudi Arabia and a few such patients were recipients of kidneys from relatives. Local, cultural or religious reasons had virtually precluded cadaver kidney transplantation in Saudi Arabia. Some Saudi patients were sent to private hospitals in the United Kingdom for cadaveric kidney transplantation where they remained for long periods without being transplanted. I was told that their treatment was extremely expensive. The physicians also stated that some Saudi patients had been sent to a hospital in a U.S. city for transplantation but for some reason they wished not to refer additional patients to that institution.

During their two-day stay at Northwestern University the physicians met with Doctor James Wolf, Chairman, Division of Transplantation, Mr. George Heidkamp, Northwestern Memorial Hospital Executive Vice President and myself, amongst others. We were sympathetic with their plight and were willing to consider having a Saudi patient await cadaveric kidney transplantation at this institution. The physicians then traveled to other transplant centers in Madison, Columbus, San Francisco, Los Angeles and Houston.

Mr. Richard Spencer, President of Uni-Med International Corporation, knew one of the physicians from Saudi Arabia and thought that his company might assist in attending to the administirative details of having Saudi patients come to this country. He requested that I be a medical consultant to assist in the development of a program that would include arranging for housing, translators and other necessities for the Saudi patients. He submitted a proposal to the Saudi Ministry of Health offering the service of his company with me as a consultant to organize a program of assisting in the placement of Saudi patients for kidney transplantation at specific U.S. transplant centers.

Mr. Spencer and I were invited to the Kingdom of Saudi Arabia in late June-early July 1981. There we met daily for five days with the Chairman and two or three members of a General Medical Committee of the Ministry of Health. The Saudi physicians were interested in the proposal submitted by Uni-Med International. They stated, however, that our request for histocompatability typing and lymphocytotoxic antibody screening on each patient prior to transfer to the United States was not possible since no laboratory would provide such services in Saudi Arabia. We maintained that in all fairness to any participating U.S. institution medical information about each prospective patient should be provided to U.S. physicians prior to transfer to this country. I agreed to prepare a data sheet in which basic information would be provided by Saudi physicians about prospective transplant candidates. I was confident the New York Blood Ctr. Tissue Typing Laboratory would be pleased to receive samples from Saudi Arabia for histocompatability typing and lymphocytotoxic antibody screening. The Saudi physicians who traveled earlier to the U.S. had stated that they had been well received at several U.S. transplant centers which indicated interest in accepting patients from Saudi Arabia. We contended, however, that additional qualified centers become participants of the program so that at no center would Saudi patients represent more than 5-10% of the total number to be considered for transplantation.

Neither the Saudi Minister of Health nor the Chairman and members of the General Medical Committee wished to consider Uni-Med's proposal of expanded social services for the patients arriving in this country as the visited U.S. institutions indicated to the physician delegation that they were experienced in accommodating foreign patients with chronic renal failure. They did accept and entered into an agreement with Uni-Med for screening of patients with chronic renal failure. Those patients deemed eligible would be referred to participating centers. Uni-Med was to monitor all charges by participating institutions so that only standard fees and bills be submitted for reimbursement.

On my return to the United States I prepared a data sheet acceptable to physicians and surgeons at several institutions which had expressed interest in receiving Saudi patients. The SA/US Patient Data Form (Attachment A) is a result of that effort and was submitted to the General Medical Committee to be distributed to Saudi physicians dialyzing patients with chronic renal failure.

Doctor Marilena Fotino, Director, Tissue Typing Laboratory of the New York Blood Ctr. Tissue Typing Laboratory, agreed to provide services of her laboratory to determine histocompatability typing and lymphocytotoxic antibody screening on blood samples to be received from Saudi Arabia. She specified the type of blood, suitable containers and condition for transport of that material to the Untied States. Uni-Med arranged for a messenger service to pick up these samples on their arrival in New York JFK Airport and deliver them to the Tissue Typing Laboratory. Although the Saudi General Medical Committee believed the intercontinenetal transfer of such samples would not be possible within two months after some technical failures, an initial sample from Saudi Arabia arrived in New York and was successfully typed and screened. Copies of the results of a specific patient's sample of histocompatability typing and lymphocytotoxic titers are submitted as Attachment B and C.

While we were developing the mechanism for Saudi patient referral I had an opportunity to speak with two transplant surgeons who had agreed to accept Saudi patients when the delegation visited the United States in February 1981. They were sent Saudi patients shortly after the delegation returned to Riyadh. One surgeon told me that his patient from Saudi Arabia had arrived with severe hepatitis and was dead within one week of his arrival. The other was angry because one of two patients sent to his center had a high lymphocytototxic antibody titer. He wanted that patient to return to Saudi Arabia because the possibility of finding a cadaver kidney for such a highly sensitized patient was remote. That patient, however, was unwilling to return. It was precisely these types of problems that we wished to avoid by organizing the program which was coordinated with the Saudi Arabian Ministry of Health.

By September 1981 the first completed patient data form, lymphocytotoxic antibody titer and histocompatability typing information were provided to a transplant surgeon at an institution which wished to consider Saudi patients. That surgeon reviewed the data and accepted the patient for consideration of cadaveric renal transplantation at a mutually agreed time. Acceptance and other instruction was sent by telex to the Chairman of the General Medical Committee in Riyadh.

As patient data forms and blood samples from other Saudi patients were received additional transplant centers were contacted about their willingness to consider transplanting Saudi patients (Attachment D).

The centers participating in this program are listed in Attachment E. Each patient (identified by initials) screened and sent to the U.S. by the above described mechanism is recorded through the end of August 1983 when by mutual agreement Uni-Med International terminated its contract with the Saudi Arabian Ministry of Health. Coordination and placement of patients has been assumed by the Saudi Medical Health Office in September 1983.

At least 92 completed patient data forms and samples of blood for typing and lymphocytotoxic antibody screening were sent to the United States from Saudi Arabia over a two-year period. Seventy-five patients have been placed at 19 centers since September 1981. Seventeen patients had high lymphocytotoxic antibody titers and were never considered for placement in U.S. centers. Seven were returned to

Saudi Arabia; one was homesick, the others had medical contraindications for transplantation. Forty patients of those who traveled to U.S. centers were transplanted; eight rejected their transplants; two by mutual agreement with their transplant physicians and surgeons elected to return to Saudi Arabia for maintenance dialysis. The others remained in the United States dialyzing to await a second opportunity for kidney transplantation. To the best of our information one patient placed by us died post kidney transplantation in the U.S.; a second patient who returned to the Kingdom with a functioning kidney expired there.

We are pleased with the success of this international medical effort. Physicians and surgeons in this country have provided specialized medical services to patients from another country where such treatment is unavailable. The physicians and surgeons and their staff at the participating U.S. medical centers have given consideration and aid to uprooted sick Arab patients. Despite overwhelming cultural and social differences these patients, many of whom are illiterate, have been the recipients of compassionate and human treatment.

Not always does the image we project abroad put our country in a favorable light. I believe I speak for all my colleagues at the participating U.S. centers in expressing pleasure and satisfaction in the results of this organized program.

ATTACHMENT A

S.A.-U.S. PATIENT DATA

PATIENT NAME: ______________________

DATE OF BIRTH: ______________

ADDRESS: ______________________

TELEPHONE: ______________

SEX: ________ MARITAL STATUS: ________

I.D.#: ______________

NEXT OF KIN IN S.A.

NAME: ______________________

RELATIONSHIP: ______________

ADDRESS: ______________________

TELEPHONE: ______________

DIAGNOSIS

RENAL ________

BIOPSY PROVEN? ________

RELATED CONDIT. &/OR COMPLIC. ____

DEGREE OF RENAL IMPAIRMENT

BUN, Cr or Ccr: ________

CURRENT STATUS OF PATIENT

STABLE, AMBULATORY & REHABILITATED ___

AMBULATORY BUT NOT REHABILITATED ___

SEDENTARY - NEEDS ASSISTANCE ___

DEPENDENT ON OTHERS ___

PROBLEMS DURING OR BETWEEN DIALYSES

EXCESSIVE WT. GAIN ________

HYPERTENSION ______ HYPERKALEMIA ______

HYPOTENSION, N. & V. WITH DIALYSIS ______

DIET: ______________________

FLUID RESTRICTION/24 HRS: ________ML.

ULCER OR HISTORY OF UPPER G.I. BLEED. ___

EVIDENCE OF PULM. OR OTHER TB ___

EVIDENCE OF LOWER URINARY TRACT ABNORMALITY

BILHARZIASIS ___

EVIDENCE OF EMOTIONAL INSTABILITY ___

CARDIOVASCULAR PROBLEMS: ARRHYTHMIA ___ ANGINA ___

PAST HISTORY: ______________

PRIOR SURGERY: ______________

PRIOR TRANSPLANT: ______________

TRANSFUSIONS, APPROX.#: ______________

DATE OF 1ST DIALYSIS: ______________

FREQ/WK: ________ HRS: ________

TYPE OF HEMODIALYZER: ______________

HEPARIN DOSE: ______________

HEIGHT (CM): ________

	BLOOD PRESSURE	WEIGHT (KG)
PRE DIAL.		
POST DIAL.		

BLOOD TYPE: ________ HEMATOCRIT: ______

HLA TYPE: ______________

% LYMPHOCYTOTOXIC ANTIBODIES: ________

EVIDENCE OF HEPATITIS ______________

HEPATITIS ANTIGEN POS.______ NEG.______

K.U.B. (to be returned with this form)

HISTORY OF URINARY TRACT ABNORMALITY OR RECONSTRUCTIVE PROCEDURES

CURRENT MEDICATIONS AND DOSAGE: ______________________________

COMMENTS OR OTHER PERTINENT DATA CAN BE COMPLETED ON REVERSE SIDE.

ATTACHMENT B

THE NEW YORK BLOOD CENTER, INC.

310 EAST 67th, STREET, NEW YORK, N.Y. 10021 (212) 570-3252
Cable Address BLOODCENT

TISSUE TYPING LABORATORY

Sent by (M.D. or technician requesting report) Dr. Peter Ivanovich

Hospital

Address 333 E. Huron
Chicago, Ill 60611

Patient's name [redacted]

NYBC Reference [redacted]

Tray (Code #)

Purpose of typing

TISSUE TYPING REPORT

Report based on results obtained with approximately 120 anti-HLA typing sera

Relationship	ABO	NAME	HLA PHENOTYPE								HLA Haplotype	Crossmatch	
			A		B		C		DR				
		[redacted]	2	28	5	7	7						

REMARKS:

Signature of NYBC physician or supervisor Arvind / Dr. Fotino

Date of typing 3/16/83

ABO RESULTS FOR OUR LABORATORY
USE ONLY

THE NEW YORK BLOOD CENTER, INC.

ATTACHMENT C

NEW YORK BLOOD CENTER, INC.

310 EAST 67TH STREET, NEW YORK, N.Y. 10021 (212) 570-3252
Cable Address BLOODCENT

TISSUE TYPING LABORATORY

t by (M.D. or technician requesting report) Dr. Ivanovich

Patient's name [redacted]

pital Chicago

Iress

Date of most recent transfusion

ANTIBODY REPORT

Leucoagglutinins: Absent Present
positive reactions/ panel cells tested
Titer: Autocontrol:

Platelet agglutinins: Absent Present
positive reactions/ panel cells tested
Titer: Autocontrol:

Lymphocytotoxins: Absent [✓ Present] weak
1 positive reactions/ 40 panel cells tested
Titer: 1/3 Autocontrol:

Remarks:

ignature of physician or supervisor Anand Menon

'ork sheet reference [redacted] Date request received 3/15/83 Date of final report 4/5

NEW YORK BLOOD CENTER, INC
3/78

ATTACHMENT D

May 27, 1982

H. Myron Kuffman, M.D.
Director Transplantation Section
Professor of Surgery
Medical College of Wisconsin
9200 W. Wisconsin Ave.
Milwaukee, Wisconsin 53226

Dear Myron:

This letter is to confirm our telephone conversation concerning the Saudi Arabian/U.S. cadaver kidney transplant program. A company in the health care field, Uni-Med International of Miami has been contracted by the Ministry of Health of Saudi Arabia to assist in the placement of Saudi Arabian dialysis patients in U.S. transplant centers for consideration of cadaver kidney transplantation. Uni-Med International in turn has asked that I oversee that patients suitably evaluated in Saudi Arabia are matched with appropriate transplant centers in the United States. We have insisted that certain clinical data and lymphocytotoxic antibody screening be provided on each patient potentially transplantable. Enclosed is a completed patient data form and the HLA typing results of a Saudi patient. The lymphocytotoxic screening is as yet not completed.

Once your center has accepted a patient the Saudi Arabian Ministry of Health authorizes the Embassy of the Kingdom of Saudi Arabia to pay all standard hospital, dialysis and physician and surgeon fees related to that patient's care. Your institution must mail a copy of all billings to Uni-Med International Corporation, 2934 Jackson Ave., Miami, Florida 33133.

Should the Medical College of Wisconsin transplantation service be willing to consider such patients we would strive to provide you with suitable stable patients who would meet your own criteria for acceptance. Please let me know if there are any patients e.g. those who are Australian antigen positive you would not wish to consider for transplantation.

Warm regards.

Sincerely,

Peter Ivanovich M.D.

PI:lf
enclosures
cc: R.T. Spencer
Uni-Med International

ATTACHMENT E_1

U.S. CENTERS & SAUDI PATIENT STATUS

INSTITUTION	PATIENT	ARRIVAL DATE	TRANS-PLANTED	CURRENT STATUS	RETURNE
Albany Medical College					
	SAR	11-24-82		Dialyzing	
	AASA	5-20-83		"	
Children's Hospital - Boston					
	MKH	8-1-83		"	
	FKH	8-1-83		"	
Children's Hospital - Los Angeles					
	AZ	5-22-82	10-15-82		
	SA	11-25-82	1-30-83		
	BHA	12-9-82	5-18-83		
	SS	1-7-83	6-9-83		
Cleveland Clinic					
	SA	2-22-82	4-3-82		9-10-82
	ASAH	10-20-82	3-3-82		
	MYMA	1-10-83		"	
	SOB	8-10-83		"	
Cornell University					
	HMS	11-17-82	2-12-83		
	NS	4-26-83		"	
Downstate Medical Center					
	HAT	3-27-83	6-23-83	Rejected	
Evanston Hospital					
	MZ	7-28-83		"	
	IMA	8-21-83		"	
Georgetown University					
	GFOA	8-30-82	6-17-83		
	AMA	5-10-83	7-14-83		
	MMA	7-13-82		TB	2-83
Henry Ford Hospital					
	MHE	11-23-82	3-1-83		6-16-83
	AYM	5-5-82	9-16-82		3-2-83
	MHZ	2-16-82	5-15-82		11-22-84
	HMF	2-2-83		"	
	MHA	5-10-83		"	
Medical College of Ohio					
	AKM	5-25-83			
Methodist Hospital - Houston					
	JG	2-24-83		"	
	AMA	6-6-83		"	
Ohio State University					
	ERA	12-16-81	12-4-82		
	WSA	7-15-82		"	
	GMAH	8-23-82		"	
	AHM	1-18-83	5-29-83		
	SA	1-25-83		"	

ATTACHMENT E_2

INSTITUTION	PATIENT	ARRIVAL DATE	TRANS-PLANTED	CURRENT STATUS	RETURNED
St. Vincent - Los Angeles					
	MMA	12-24-81	2-20-82	Dialyzing	
	FA	2-4-82	3-9-82		
	MAL	4-4-82	11-22-82		
	FMHE	7-26-82	9-12-82		1-26-83
	ASA	9-26-82	11-17-82		4-7-83
	AS	9-22-83	12-15-82	Rejected	
	SA	11-26-82	12-19-82		4-19-83
	HAI	6-2-82	12-2-82	Rejected	
	AAJ	3-1-83	3-31-83	Rejected	
	AAR	2-28-83	5-13-83	Rejected	
	ANA	4-27-83	6-30-83		
	LMA	6-26-83		"	
	ASAB	6-8-83		"	
	YMAA	6-10-83		"	
	LEK	5-3-82	9-26-82	Deceased	
	ASAS	6-7-83		Homesick	7-15-83
St. Vincent - New York					
	AB	8-4-83		"	
University of California San Francisco					
	GMH	2-16-82	7-28-82		3-17-83
	AMS	2-16-82	6-27-82	Rejected	
	SS	6-26-82	1-22-83		8-30-83
	MSA	5-23-82	2-16-83	Rejected	
	ND	11-17-82	5-27-83		
	SAM	3-16-83		"	
	MAHA	8-26-83		"	
	FMU	8-28-83		"	
	ASA	5-21-82		TB	10-28-82
	MAMA	8-16-82		TB	10-15-82
	MAHI	8-16-82		TB	10-15-82
	KAM	3-2-83		Not suitable	1983
University of Cincinnati					
	RAS	6-28-82	7-14-82		2-19-83
	AAA	7-28-82	8-13-82		6-30-83
	AAA	10-23-82	12-11-82	Rejected	6-10-83
	MAMS	2-16-83	5-1-83		
	SMA	5-27-83		"	
	NMA	6-6-83		"	
	LMA	6-26-83		"	
	SARE	10-25-82		Hepatitis	11-23-82
University of Pittsburgh					
	MAA	3-1-82	11-6-82		
Washington Hospital Center					
	FSA	2-8-83		"	
	RMA	2-9-83	5-3-83		
	AAA	4-6-83	7-8-83		
	AMA	3-8-83	5-19-83		
	AH	8-1-83			

Mr. GORE. Thank you very much. As I noted, we will hold questions until the other panelists have made their statements.

I would like to call next on Ernest Bauer, who is chairperson of the Patient Action Committee, within the ESRD Network 23, based in Washington. Mr. Bauer, we are delighted to have you here and look forward to your testimony.

Mr. BAUER. Thank you, Mr. Chairman.

I have some copies of my statement which I neglected to put over on the adjoining table.

Mr. GORE. Fine. We'll have someone pick them up.

Mr. BAUER. I would appreciate them being made a part of the official record of this hearing.

Mr. GORE. We have already done so.

Mr. BAUER. I am Ernest T. Bauer, and I come before this subcommittee today as the chairperson of the Patient Action Committee of the End Stage Renal Disease Network No. 23 of the National Capital Area. Networks, as you know, were created by the Congress to help advise the U.S. Department of Health and Human Services on renal matters, and their membership includes medical professionals from all corners of the renal community, as well as consumers and patients. I might say parenthetically, Mr. Chairman, that networks are for us patients very useful. They are the only real forum for discussing generic renal issues with health care professionals.

From a medical standpoint, I am a renal transplant patient, having been transplanted 6 years ago with a kidney from a living related donor, my sister. Before that, I spent 5 years on home hemodialysis, and my wife was my partner.

I understand that one of the purposes of this hearing is to solicit comments from and listen to the reaction of patients to a recently discovered phenomenon of an increasing number of non-U.S. residents receiving kidney transplants in the United States. I am told that in network 23, which includes the District of Columbia, northern Virginia, and lower Maryland, there were five such kidney transplants done on nonresidents in 1980. The number grew to 14 in 1981, and to 31 transplants in 1982. Thus, the growth has been rather significant and precipitous.

The 1982 number, that is, 31 transplants, represents 25 percent of the total kidney transplants performed in the National Capital Area for that year. For some individual hospitals in network 23, the figure could go as high, I am informed, as 50 percent of all kidney transplant operations performed. On a national level, however, the situation is less severe, amounting to approximately 10 percent of total renal transplants. But this, in my opinion, is still significant.

I hear that the majority of the nonresidents receiving kidney transplants in the United States have been from Greece and Saudi Arabia. These patients generally come to the United States for such surgical treatment under the financial sponsorship of their central governments.

I feel that patients in the United States would have two reactions to these facts. First, because these nonresident patients can pay cash generally for such surgical procedures, and can probably afford to pay much more than what is generally allotted under the normal insurance coverages of medicare—which is approximately

$20,000 per operation—it is conceivable that they are being advanced on the organ transplant waiting list ahead of some U.S. residents.

Also, while patients who are U.S. residents are very carefully matched as to blood type and tissue type before being given a kidney, so that there is at least a two antigen match for each kidney transplant, my understanding is that frequently these patients are being transplanted with a zero antigen match. By virtue of this practice, these nonresidents become much easier to match locally—that is, a zero antigen match is much easier than a two-out-of-four antigen match—and they can, therefore, get a kidney or whatever other organ is to be transplanted much easier, and, of course, much more quickly in the overall process. These kidneys, therefore, are not made available to the larger pool of patients in the United States waiting for kidneys. While I have no personal knowledge that this has happened yet, such a scenario certainly seems to be a real possibility to me.

Also, because these nonresidents come here under the financial sponsorship of their home governments, they can presumably avail themselves of the latest in immuno-suppressive drugs such as cyclosporin-A. This drug, as you probably know, is reputed to be very successful in preventing transplanted organ rejection, but is reputed to cost over $5,000 per year per patient and is not covered by medicare and, therefore, is beyond the financial means of many U.S. residents who are facing these catastrophic medical expenses themselves.

The second reaction I think patients might have to this phenomenon of the alarming increase in the number of nonresidents receiving kidney transplants in the United States, is that the procedures and institutions of which they are taking advantage were put into place by the Congress primarily to help American citizens and U.S. residents. If, in fact, U.S. residents are receiving needed organ transplants later than they might normally, or are being bumped to a lower position in the cadaveric kidney transplant waiting list, this practice, it seems to me, is wrong and an affront to U.S. residents. While I recognize that the United States and its medical community might very well have an international responsibility and obligation to be compassionate, cooperative, and helpful to other peoples and other nations, by sharing such transplant surgical technology, the first responsibility it seems to me ought to be to U.S. citizens and U.S. residents.

In the picture which I have just painted for you, I submit that U.S. residents could be losing benefits which are more rightfully theirs. I also feel strongly that the U.S. organ donor program, with which the Congress is in sympathy and which it has encouraged, could be severely undermined. Perhaps what is needed is some national program to monitor and lay down standards for the harvesting and procurement of transplantable organs to assure that U.S. residents get served first, and that we as a country establish our national priorities in these matters. Also, it seems to me that the medical profession should be required to make public their records in such important matters under a kind of medical sunshine law, if you will, or Freedom of Information Act, so that U.S. patients can make more intelligent decisions regarding their own health care.

That completes my statement, Mr. Chairman. Thank you.

Mr. Gore. Thank you very much. We will hold off on questions until we've heard our final two witnesses.

I would like to call now on Miss Barbara Lindsay from College Park, Md., who will also give us a statement from the perspective of patients.

Ms. Lindsay. Chairman Gore, members of the committee, participants, and observers, I, too, am a member of ESRD Network 23, Patient Action Committee. Thank you for this opportunity to speak to you today.

In April of this year I was unable to attend the hearing but did submit material on the subject of organ transplants, medicare coverage, and disability regulations. In addition to my comments, there was a paper authored by the Patient Action Committee of ESRD Network 23, of which I am a member, on medicare coverage recommendations for transplant patients. Also included was a summary of the findings of a health care finance agency task force on rehabilitation. Of particular interest to your hearings was the report of the subcommittee on financial disincentives, on which I serve. I hope the committee found this material beneficial.

In presenting my testimony today, I think it is relevant to introduce myself and explain the reasons that have brought me before you today. I have been personally involved with some aspect of renal disease since early 1971, when my own kidneys began to fail after a complicated stillbirth pregnancy. At that time I was told by the physician that each of us is given only one set of plumbing and to make the best use of what I had because when it was gone, there was nothing that I could do.

How fortunate that he was wrong. In the years that followed I experienced many different methods of treatment, from aggressive drug and diet therapy, peritoneal dialysis, and hemodialysis. They were not very successful and I was completely debilitated.

In March 1977, I received a kidney transplant. While an organ transplant is not a complete cure, it is for me the best method of treatment. It is impossible for me to emphasize enough my appreciation for this second chance. Therefore, it is important to me that everyone who can and wants an organ transplant should have such an option available.

At present, public awareness of the importance of passing life on through organ donation has not kept pace with the demand. Even with an available organ, there are inequities in the delivery system and the questionable practice of providing organs to persons of other countries while the American patient, who has a vested interest in this country, may have to wait.

Since receiving a transplant, I have been active in the renal community. The ESRD Network has provided a forum where I and others can bring our problems and concerns. The network has provided a cohesive element and has been a positive contribution to the community.

Some of the information that I will relate to you today has been provided by patients who are dependent on the medical community for life sustaining treatment. They have expressed fear of possible repercussions. They do not wish to jeopardize their welfare. I have been told of patients who have complained of some treatment practice and then found that the matching requirements for an organ for them have been changed, making it harder to find a suitable match to meet the new criteria. I am not here to comment on the justification of their fear; only to assure you that their fear is real. For this reason, I will endeavor to be their voice, deserve their trust, and protect their anonymity.

The public is only now beginning to overcome philosophical, religious, and emotional aversion to donation of organs for transplant purposes. Supply falls far beyond the demand. In 1982, only approximately 3,500 of the 10,000 waiting for an organ received one. Organs are a natural resource and, as such, their use must be carefully considered. Those very Americans who are beginning to understand the need and benefit of donation of organs are not enthusiastic about sending them or giving them to people from other parts of the country before providing them first to Americans.

It is my understanding that in California there are a number of kidneys being shipped to Japan. Public opinion has reacted so strongly against this practice that a number of persons who have indicated that they would like to be an organ donor have now written resident only on their driver's licenses in an effort to insure that the organs will be offered to persons in this country first.

In an example closer to home, I have discussed the situation of organ transplants to nonimmigrant aliens with my mother. She is a woman who understands the importance of organ donation and has seen firsthand the benefits of organ transplantation. Yet she feels very strongly that the United States has an obligation to help its own first. On more than one occasion she has stated emphatically that if she thought her organs were going to be used for a nonimmigrant alien, before making every effort to find a suitable recipient among those Americans waiting, she would want to withdraw as a potential donor. I do not think that her feelings are an isolated case. As the public becomes more aware of the potential for inequities in the present system, they will be discouraged as potential donors and this will do irreparable damage to an organ procurement program.

Renal disease has become big business. An American patient maintained on one of the modes of treatment other than transplantation provides guaranteed moneys that are largely subsidized by the Federal Government. This program is a literal lifesaver for most people who cannot afford the cost of such a catastrophic illness. Once they receive a successful transplant, medicare coverage in most cases is terminated. There is no incentive for some of the medical community to recommend an American in this system for a transplant. The nonimmigrant alien is not a part of this medical insurance program. The financial advantage that he provides is one of immediate and full cash payment for services. It is rumored that the nonimmigrant alien may pay as much as double the amount mandated under the Government reimbursement scale. This situation provides a possible potential for abuse.

Renal patients jokingly tell me tales of patients who come to this country specifically for medical treatment that they cannot receive at home. They arrive with a valise of money and count out the cash payment after each treatment. Like most jokes, there is a bitter ring of some truth and the attempted humor is only to hide resentment and tears of frustration.

The burden of nonimmigrant aliens on the system has been felt at the State level. In talking with an official of the Maryland kidney disease program, I learned that prior to a change in eligibility requirements, Maryland, one of only a few States in the union that has established a funding program to supplement prohibitive expenses of renal treatment, was paying substantial bills for nonimmigrant aliens residing in the State.

At that time the only requirement was that you reside in the State of Maryland in order to have the State pick up those medical costs not covered by insurance. The nonimmigrant alien has no insurance. Because of Maryland's proximity to the Nation's Capital, and the large number of Embassies found there, Maryland received numerous inquiries and applications for assistance.

In 1982, the Kidney Commission of Maryland, funded 100 percent by State moneys, paid $400,000 for treatment of 11 nonimmigrant aliens. In December 1982, the regulations were changed to require a person to be a citizen of the United States or on a permanent visa in order to qualify for State funds. When the intention to change the regulations became known, there was a noticeable increase of inquiries from nonimmigrant aliens and Embassies acting as their agents. Since the change in the regulations, the Maryland Kidney Disease Commission has turned down 10 applications.

Other countries seem to have faced the same problems that we are addressing here today. Although my inquiries to the board of health in London are not complete at this time, it is my understanding that they found it necessary to pass restrictive legislation under their Human Tissue Act. This was done to deal with the increasing problem of preserving a limited supply of organs in the face of a large influx of nonimmigrant aliens.

I became alerted to the possible similarity of our problems from a friend who does a great deal of traveling. While dialyzing for a period of time in Great Britain, frequent discussions with the medical staff revealed that at one time the country was flooded by nonimmigrant aliens, particularly from the Middle Eastern countries, where religion allows them to receive an organ but forbids them to donate their own body parts for the purpose of receiving organ transplants. In order to preserve their limited supply of available organs, Great Britain passed legislation limiting organ transplants to British citizens.

Under our present system, the American patient may not be receiving the best possible chance for organ transplantation, but the nonimmigrant alien, who has come here specifically for medical treatment, is not necessarily getting the best deal, either. In his eagerness to receive a transplant, he may settle for an organ of questionable suitability. This organ may reject and he may find it necessary to undergo several transplants before receiving a viable graft. Each time he pays a large sum of money, undergoes a painful procedure, and takes the surgical risks. With each transplant, the body builds up antibodies, reducing each time the number of organs that his body will tolerate. In addition, each time he receives a transplant, it removes one more organ for availability for someone else.

Perhaps the nonimmigrant alien is not advised of the conditions of compatibility, but the American patient probably is. This is one of the reasons that those who need transplants in this country adhere to the recommended requirements for more extensive testing and standards to be met before accepting an organ.

The American and the nonimmigrant alien are both potential losers under the present system. Only some members of the medical community, which get paid for each procedure regardless of success, are the ones that profit.

There is another unfortunate aspect of the transplanting of nonimmigrant aliens. Under the present system, there is no way of determining the survival of a patient or his graft once he leaves this country. This represents the loss of valuable data that can provide needed answers to the treatment of future transplants.

At this time the actual surgical implantation of an organ is not particularly difficult. The real success of a transplant is found in the method of followup treatment. Even in the 6½ years since I was transplanted, there have been many changes in the state-of-the-art. Many of these changes are based on the information to be learned from the data collected by the networks on previous transplants. This is what we call progress.

Do American patients find themselves waiting longer for transplants? The number of cadaver transplants steadily increased in the year since networks began collecting data. The Washington area network study shows that in this area the percentage of nonimmigrant aliens has tripled. The percentage of Americans receiving transplants has remained almost the same. A patient on dialysis related to me that they observed that in their dialysis center American patients will wait for over a year, while every nonimmigrant alien that comes to this dialysis center is transplanted within a few months. Other sources within the medical community have suggested that when a nonimmigrant alien comes to them for transplants, their name is put on the top of the list for consideration. Under the present lack of standardized practices designating organ recipients, this is impossible to verify.

There are, however, a number of factors that must be considered. One, the individual physician has a great deal of discretionary power when determining who receives a kidney. This is not necessarily bad. There are some human factors that cannot conform to inflexible criteria. I do feel that perhaps the physician would appreciate some suggested guidelines to help him with what is at best a difficult decision.

Two, at present there is no national system to insure an equitable distribution of organs. I have heard it estimated that there are well over 100 different organ procurement institutions. They operate on a regional basis and have no comprehensive policy of communication or even cooperation. Delays in contacting other regions when no suitable recipient can be found in the region that has a kidney may make the age of the organ unsuitable for another better matched recipient. This results in the waste of an organ, or it may be given to a nonimmigrant alien who does not require the same criteria as set for an American patient by his physician.

Nonresident aliens do not specify a certain degree of compatible factors be met before accepting an organ. This includes antigen matches. American physicians require that certain suitable factors be present before recommending the kidney to their patient. If the nonimmigrant is less choosey, then his name may naturally rise to the top of the list of persons waiting for an organ. They find almost any organ acceptable. The search for a recipient may stop before the more selected patient is reached. If you enter the selective process indicating that you have no criteria or, more specifically, you will accept a kidney with a zero antigen match, while I state that I am only interested in an organ that has a two antigen match, your name will appear on the list ahead of mine.

The patient has the option of rejecting an offered kidney. He wants the best possible chance of success. Thus, he may become very selective, refusing an organ that may then be given to an nonimmigrant alien who does not require the same criteria.

The above explanations as to why a kidney may go to a nonimmigrant alien do not imply an abuse of the system. They only emphasize the difficulty under present practices of insuring that the correct selection is made. They are all legitimate reasons that a kidney may be given to a nonimmigrant alien. What is needed is a system of checks and balances.

Let me relate one excellent example. A person was contacted and told to stand by, that two kidneys had become available. The person contacted was considered a good possible match. Later it was discovered that both of the kidneys had gone to nonimmigrant aliens. It is impossible to determine if the person in question was the best match, whether they were passed over in favor of someone else for questionable ethical reasons, whether the two nonimmigrant aliens who received the kidneys were the best possible matches, and finally, if the nonimmigrant aliens' ability to pay a premium price in cash was an influencing factor.

The point in relating this anecdote is not to point an accusing finger. It is an excellent example of why the system needs to be reevaluated and appropriate changes made.

Thank you for your attention.

Mr. GORE. Thank you very much.

The final witness on this first panel is Prof. Warren Reich, director of the division of health and humanities, at the Georgetown University School of Medicine.

Professor Reich, we welcome you. If you care to summarize any of your statement, feel free to do so. The full text will be in the record. We are looking forward to hearing from you.

Professor REICH. Thank you, Mr. Gore. I appreciate the opportunity to make some comments this morning.

I was asked to present testimony today on ethical aspects of organ procurement, organ distribution, and organ transplant allocation in the international perspective, with special attention to the ways in which these questions relate to nonresident, nonimmigrant aliens, whom I will call simply aliens for the sake of brevity.

In my oral comments this morning I would just like to summarize my written testimony by highlighting two problems. First, how the financially capable alien, whom I will call the wealthy alien, affects the procurement and distribution of organs in the United States, and second, how the poor alien relates to American policies of organ acquisition, distribution and transplantation.

First, the wealthy alien raises several questions. A first question is this: When the wealthy alien patient, for example, a young child, is accompanied to a U.S. medical center for a kidney transplant by a live donor—for example, the patient's father—what should be done if the donor's kidney does not graft? If a second graft is attempted, must we insist that it be done only with a kidney donated from a foreign national? That would seem to be an excessive demand. The physician's ethic obliges him or her to act in the best medical interest of his or her own patient, regardless of race, nationality, or citizenship. Thus, there is a certain moral requirement arising from considerations of a professional ethic that, once having been accepted as a patient, the patient should be given a fair chance at survival and improved quality of health without discrimination.

Furthermore, that patient should have equal standing on a wait list with Americans in the sense that he does not lose his moral status as patient because the first transplant attempt was unsuccessful. So the physician is bound by the profession's ethic not to discriminate on the basis of nationality. Consequently, I believe the subcommittee should oppose any legislation or other policy that would exclude from equal access to medically sound organs available in our system those aliens who have actually gained access to our system through referral or accompanied by a live donor.

A second problem involving the wealthy alien deals with differential surgical and hospital fees for organ transplantation. Reportedly, some American surgical services charge a higher fee for kidney transplants, as much as five times higher, when the patient is a wealthy alien. Detailed information on this point is difficult to obtain, yet very important for these questions of national policy.

As justification for the differential fee for aliens, some have offered the following argument: People from that country did not contribute through the payment of taxes or in other ways to the costs of research and development that made it possible for U.S. institutions to develop this technology. This argument would seem to suggest that surgeons may, without authorization, collect funds on behalf of the republic and then perhaps appropriate for institutional and personal gain fees that are intended for public reimbursement.

I urge that if the Federal Government takes steps comparable to those proposed by you, Mr. Gore, in H.R. 4080, that it make adequate assurances that there will be a uniform fee for organ transplant services, for several reasons: To protect the rights of aliens, to preserve the professional-medical ethic, which opposes taking financial advantage of patients, but especially to protect the Federal Government from becoming a party to excessive profits if it underwrites expenses for an efficient organ procurement system.

A third kind of problem related to the so-called wealthy alien is raised by allegations that wealthy aliens have bought their way to the top of the transplant list in the United States and in so doing have displaced Americans. If this practice ever occurs—and I sincerely hope that your investigations prove that it does not—it would raise questions of unethical enrichment of the profession, unjust displacement of American patients, and the added impropriety of a fellow American physician or hospital being enriched in the process of the favoritism that may cost the American patient his or her life. Legislation of the kind that you propose should have provisions, it seems to me, against this sort of abuse.

A fourth kind of question related to what I'm calling the wealthy alien is this. The proposed legislation would apply Federal funds to the procurement and distribution of organs that would then be transplanted in aliens on a fee-for-service basis. Increasingly, American surgical and medical services are delivered in the context of for-profit corporations and other institutions. My concern is that the Federal legislation intended to improve the availability of organs should not become a device for strengthening an American market monopoly on organ transplantation in a global dimension. Consequently, I urge that legislation such as you propose, Mr. Gore, be linked with an international program of medical cooperation in which knowledge and experience will be shared, international research projects undertaken, and the skills for transplant services be shared with those of other countries.

A fifth issue arising from aliens who are financially able to become patients in an American transplant service, whether their financial ability is their own personal financial ability or given them by their government, which has, let us say, signed a contract with an American hospital, is the following: How should organs obtained in the ESRD program be allocated to aliens who have been accepted as patients in the United States? Let us consider for a moment the "Americans First" policy which has been mentioned this morning, whereby matched organs must always be offered first to American patients and only those organs not chosen for use by Americans would be grafted into aliens in our hospitals or, for that matter, would then be shipped overseas for use by aliens. If restriction of aliens to that pool of organs that have been, for whatever reasons, rejected by Americans, places them and their transplant surgeon in a situation of possibly having to settle for an organ of inferior quality, or if this provides them with options that are medically less optimal than the options available to American patients who seek a matching organ, this would be an offense against the traditional principle of ethics in medicine that the physican—and by extension, the hospital—should act only in the best medical interest of the patient. The physician must be blind to the nationality or citizenship status of his or her patient in deciding the appropriate quality of medical care, including the selection of an organ. I think legislators should preserve this ethic of medicine and, therefore, they should be in this respect suspect, somewhat suspect, of the Americans first policy.

Those are some of the issues related to what I have called wealthy or financially capable aliens, that I urge you to take into account.

The second problem deals with the poor alien. I would join others who have testified here at an earlier date in urging you to take steps to prohibit the procurement and/or distribution of organs through a system of cash exchange. In addition to several other strong ethical reasons against the purchase and sale of organs, I recommend that you consider this reason related to the international dimension:

If, for example, poor aliens were offered $10,000 to sacrifice a kidney to be made available to other people, again that might be 10 or even more times the per capita income in their country, the danger is that poor foreign nationals would be manipulated, no matter how freely they may seem to have consented, into mutilating themselves for the sake of financial gain. Furthermore, this practice would present an image of America as a Nation whose greed extends beyond the limits of victimization of the poor.

A final example of how the poor alien affects our system is this. Recently there have been some cases in which desperate poor aliens have managed to gain entry into our country and then gained admittance to the emergency room of a hospital, in which case they were then dialyzed and put on regular dialysis treatment that could, and medically should, lead to transplant in some cases. What we have operating here is an alien taking advantage of an egalitarian principle whereby lives are saved at emergency rooms without discrimination as to citizenship, but simply on the basis of their being here, of their presenting themselves in need. There are certain obligations we incur to people simply because they are here and present themselves in need.

In the recent *Plyler* v. *Doe* case in the U.S. Supreme Court, we saw a similar egalitarian principle operate in reference to nonresident, nonimmigrant aliens who sought another, less urgent service—access to a free education in public schools.

In my written testimony I have argued that we should adopt a Good Samaritan policy at the national level, a policy suggested by the American philosopher Michael Walzer in a somewhat different context, leading me to urge that the Federal Government make provision for a Good Samaritan quota in its programs for organ procurement and distribution, a quota that would be put to the benefit of the destitute alien.

My final and third comment relates to a procedural point, a recommendation that I made in my written testimony, that the Federal Government establish a national commission on the social, ethical and policy dimensions of organ procurement and distribution. I have been led to this conclusion, the need for this, because of the lack of clarity, for example, about the data regarding the shortage of organs, as well as the complex factors that I and others have raised here today. My recommendation that a policy commission be established does not imply that nothing be done until its conclusions are reached, nor does it run counter to the structures of the legislation that you propose, Mr. Gore. I would see my recommendation coinciding with your proposed National Organ Transplant Act in the following way:

The proposed National Center for Organ Transplantation would have, in your legislation, an advisory council which would conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation. I would envision the advisory council of the National Center for Organ Transplantation as the national commission that I recommend, but with these differences: The advisory council should have a more thorough-going policy recommendation function, would have to investigate matters that the proposed legislation apparently takes for granted or fails to mention, the precise extent and nature of organ shortages.

We have mentioned even today the discrepancy between patients who are waiting for organs and those who actually receive them. It seems to me that that kind of data is misleading, inasmuch as it shows an absolute shortage of organs and not a relative shortage of organs, a shortage of organs relative to matched organs and patients. I am confused about the data. It seems to me that this ought to be studied in an ongoing way.

The advisory council or commission should also examine the most effective and ethical ways of stimulating voluntary organ donation, both nationally and internationally, as well as examining always which policies would best protect the interests of Americans, while also being reasonably attentive to the needs of aliens.

Thank you.

[The prepared statement of Professor Reich follows:]

Testimony On

ORGAN TRANSPLANTATION IN INTERNATIONAL PERSPECTIVE: ETHICAL ASPECTS

Before The

Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C.
November 7, 1983

By

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He has been at Georgetown University since 1971. From 1972 to 1978 he was Editor in Chief of the Encyclopedia of Bioethics, a four-volume reference work that was the first in its field and that won the Dartmouth Medal of the American Library Association for outstanding reference work in 1979.

In 1982-83 Professor Reich was Fellow of the National Humanities Center in Research Triangle Park, North Carolina; and in 1983 he was von Humboldt Visiting Professor of Bioethics in the faculties of Medicine and Theology at the University of Tubingen, West Germany.

Professor Reich received his doctoral degree in theological ethics at the Gregorian University in Rome. He has published widely in the area of bioethics.

Thank you, Mr. Chairman and Members of the Subcommittee, for inviting me to address you on ethical aspects of the procurement and allocation of human organs for transplantation, with special attention to the ways in which we ought to relate to non-residents aliens in these matters. I believe your Subcommittee is addressing a problem that is not only timely but also important in terms of the public good and the moral character of our nation. I hope that my comments will be useful to you.

I am Professor of Bioethics in the School of Medicine at Georgetown University and Senior Research Scholar in the Center for Bioethics in the Kennedy Institute of Ethics, also at Georgetown University, where I was Editor in Chief of the "Encyclopedia of Bioethics," the first comprehensive reference work for this field. During this past year (1982-83), as Fellow of the National Humanities Center (in Research Triangle Park, North Carolina), I was able to investigate questions directly related to today's hearings: our obligations with respect to the critical care of aliens, with special attention to organ transplantation. My doctorate is in theological ethics. However, my remarks will not focus specially on the religious dimensions of organ transplant, but rather more generally on those moral and ethical issues that have a bearing on public policy in these matters. While many of my comments will be applicable to the acquisition and allocation of any human organs, I will focus especially on the human kidney.

I. PROCEDURAL RECOMMENDATION

I begin with a procedural conclusion. My examination of the ethical aspects of organ procurement and transplantation in reference to the non-resident, non-immigrant alien (whom, for purposes of brevity, I will refer to simply as the alien) leads me to conclude that the issues are extraordinarily important, even potentially explosive. Yet it is very difficult to make a judgment and recommendations on how to respond in the public policy forum to several of the issues that I will presently discuss, for we have inadequate data and assessment of data on such crucial matters as: organ shortage nationally and internationally; professional and hospital practices in the area of according priority to aliens vs. U.S. citizens and residents; and professional and hospital practices in the area of fee-setting and differential fees for aliens vs. U.S. citizens and residents. More fundamentally, we lack a coherent political philosophy on how we should relate to those aliens who seek access to our country for the advantages, including the lifesaving advantages, that we have to offer. Finally, we have never, as a matter of national concern, thoroughly examined the political implications of organ transplantation and other related biomedical technologies, in the setting of a sustained, interdisciplinary study that focuses on public policy requirements. Consequently:

I urge that a national commission be established to examine thoroughly and make public policy recommendations regarding the social and ethical implications of organ procurement and distribution, in reference to U.S. citizens and residents as well as non-immigrant, non-resident aliens. It would seem to make most sense to frame this inquiry into allocation of organs and organ transplantation within the larger issues of economic allocation and high-technology medicine. These important issues are not being adequately attended to by the federal government.

(Several commissions have investigated and made recommendations on public policy dimensions of various problem areas in biomedical research and medical practice: e.g., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; the Ethics Advisory Board of the DHEW (DHHS); and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. None of these Commissions has, however, directly examined the topic of organ transplantation in ethical and public policy dimensions.)

Because of the urgent nature of lifesaving transplant efforts, the proposed study should not be an excuse for relenting in efforts to stimulate organ donation and the efficient distribution of organs. Furthermore, results of the commission's study should be promptly and effectively put into practice.

The hearings that were conducted by this Subcommittee in April of this year (U.S. House of Representatives, Ninety-Eighth Congress, First Session, Organ Transplants, Hearings before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, April 13, 14, 27, 1983, Washington, D.C.: U.S. Government Printing Office, 1983), as well as these current hearings go a long way toward identifying the issues, positions, and resources for such an examination; but in view of the complexity of the issues, they are not sufficient for determining an appropriate range of public policies.

II. PRELIMINARY ETHICAL ISSUES

1. The Question of Scarce Kidneys

An important assumption in discussions of international aspects of kidney transplantation is the scarcity of these organs. Thus, it is frequently argued that aliens should not be allowed to compete with Americans for American kidneys, since there is a shortage of kidneys for our own people. It is further claimed that many problems of access to kidney transplants would be solved if we could increase the supply of human kidneys suitable for transplant.

Yet the existence of a shortage, its precise nature, and its implication for treated and untreated aliens and citizens do not seem to be all that clear. For example, it is frequently and widely claimed that the number of kidneys available falls far short of the number of people who require or await a kidney transplant. From this observation it is concluded that large numbers of Americans (not to mention non-resident aliens who may be seeking an American transplant) must remain untransplanted, their lives sustained by renal dialysis, which for those patients is less desirable.

Questions can be raised about such an assessment of kidney shortage. We need to know, for example, what percentage of those who "await" a kidney cannot be transplanted at all, due to medical or immunological difficulties, i.e., how a shortage in absolute numbers of kidneys compares with a shortage in matched donors and recipients; to what extent rejected organs are medically useable; how the most recent developments in overcoming immunological barriers affect earlier statistics on organ availability; and what sorts of motivations, stimulation of volunteerism, and legislation might increase organ availability. At the same time, especially in light of the international dimensions of organ procurement, further consideration is needed of methods that might stimulate increased voluntary donation of organs on an international scale, within ethical restrictions, and an easier flow of those organs internationally.

Consequently, I urge that a comprehensive study be made of the shortage of organs, in light of the ambiguities in the data mentioned above; yet because of the urgent nature of lifesaving transplants, that efforts be continued to stimulate and coordinate the procurement and distribution of organs.

In the remainder of my remarks I will, however, assume that there is a shortage of kidneys and that improvement in organ procurement would significantly contribute to the prompt and effective medical treatment of end-stage renal disease (ESRD) patients.

2. Definition of Death

Assuming that there is an inadequate supply of cadaveric organs for transplant purposes, the problem could be alleviated by legislation at the state level. I am referring to the need for legislation in those states that have not yet enacted a law recognizing irreversible cessation of brain function as the major determinant for the definition of death. I do not advocate the brain-oriented death criterion primarily to facilitate the harvesting of human organs. Rather, it now seems clear that older definitions of death based on cardiopulmonary function without adequate attention to the role of brain function are not consistent with a contemporary understanding of the nature of death and with the technological capabilities of medicine. Continued use of the traditional criteria easily leads to abuse of the patient, as when cardiopulmonary functions are being indefinitely prolonged by artificial means even after the individual has suffered brain death.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research has advocated the legal adoption of a criterion of brain death, as have other professional and public study groups. Without such legislation, ethical and legal doubts may sometimes prevent physicians and nurses from making inquiries about organ donations. Uniform legal adoption of the brain-oriented definition of death would greatly enhance the availability of cadaveric organs--for use not only by U.S. citizens and residents, but also by non-resident aliens whom it is right for us to treat. For these reasons, I urge you to encourage the states to enact the Uniform Definition of Death Act. (See U.S., President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Defining Death, A Report on the Medical, Legal and Ethical Issues in the Determination of Death, July, 1981, Washington, D.C.: U.S. Government Printing Office.)

III. PROCUREMENT OF ORGANS

1. Live Donor Transplants

One method of organ acquisition and distribution is live donor transplant, a method that does not create competition for kidneys that have been acquired from human cadavers. Nonetheless, some ethical and policy issues may arise regarding live donor transplants in international perspective.

If an alien patient, e.g., a young child, is accompanied to a U.S. medical center for kidney transplant by a medically screened donor, e.g., the patient's father, what should be done if the donor's kidney does not graft? Would we be justified in insisting that if a second graft is attempted, it be done only with a kidney donated from a foreign national? That would seem to be an excessive demand. After all, the patient is now here, actually under the care of U.S. physicians. The physician's ethic obliges him or her to act in the best medical interests of his or her own patient, regardless of race, nationality, or citizenship. Thus, there is a certain moral requirement, arising from considerations of compassionate professional care, that once having been accepted as a patient, the patient should be given a fair chance at survival, without discrimination. Should this alien patient have equal standing with needy

Americans who are already on the kidney wait-list? Yes. He does not lose his moral status as patient because the first transplant attempt was unsuccessful; and the physician is bound by the profession's ethic not to discriminate on the basis of nationality. Consequently, when kidney procurement through live donor transplant is a condition of an alien patient's access to an American transplant service, this does not offer justification for refusing the patient an "American kidney". The patient who gains access to our transplant service system on the basis of live donor kidney transplant that fails is already within a relationship of moral responsibility, and thus differs sharply, from an ethical perspective, from the numerous, potential, unidentified ESRD patients who would benefit by an American transplant.

Therefore, I urge the Subcommittee to oppose any legislation or other policy that would exclude from access to medically sound organs available in our ESRD system those aliens who gained access to our system through referral and accompanied by a live donor.

2. Purchase and Sale of Organs

It has been proposed that human organs be obtained by purchase and distributed by sale of the organ. In an international perspective, American individuals, firms, or organizations might purchase organs from aliens who are citizens of another country or of no country. Those who favor harvesting organs (e.g., in foreign countries) and then re-selling them argue that this practice is justified because it would make more life-saving organs available.

Ethical objections against this policy are of two kinds. First, there is the argument that cash systems appear to be the least just, for the poor become the major suppliers of organs, since the financial motive directly touches their economic situation. Indeed, the danger is that poor foreign nationals would be manipulated, no matter how freely they may seem to have consented, into mutilating themselves for the sake of financial gain. For the profit offered them for sacrificing a kidney (say, $10,000) might be ten or twenty times the per capita income in that country.

Furthermore, the practice would reflect unfavorably on the moral reputation of America, the source of the proposed policy, for it would present this country as a nation whose greed extends beyond the limits of victimization of the poor. Finally, this method would be least just, because poor aliens are least able to afford the organ transplant when they need it.

The second argument against the practice is perhaps implied in the first. To trade commercially in body parts is to treat the human body as a mere commodity and thus to demean the dignity of the human person.

I find more convincing from an ethical perspective the procurement of organs through a voluntary, unpaid system in which one's organ is regarded as a gift of the self to either an identifiable or an unknown neighbor. The gift of life, or the gift of self, carries with it its own special value. But beyond that, when a donor realizes the benefit that his or her gift brings to the needy relative, the ethnic brother, the sister co-religionist, or simply the unknown beneficiary, and when the donor additionally realizes that there are other givers of life in the human community, the result is the creation of social solidarity, the encouragement of altruism, and the promotion of community consciousness.

Thus, the strength of the argument for voluntary organ donation is not found simply in the appeal of an ideal; rather, it is a question of national character, of community virtue, in a world which increasingly becomes a single global community. The voluntary approach is important and preferred because it flows from certain assumptions about what sort of community our nation should be, whereas the financial quid pro quo method tends to atomize individuals in their separate and competing worlds of self-interest.

On the basis of these value considerations, I urge the Subcommittee to take steps to prohibit the procurement and/or distribution of organs through a system of cash exchange.

It should also be pointed out that aliens being transplanted in this country may be asked to pay a higher-than-customary price for the costs connected with organ procurement, transport, and testing--a higher price that may conceal the sale of the organ. For the same moral reasons suggested above, we should be alert to exclude the concealed sale of organs from our medical and surgical transplant services.

IV. ALLOCATION OF ORGANS AND OF ORGAN TRANSPLANTATION

1. Differential Surgical and Hospital Fees for Organ Transplantation

One aspect of the market mechanism for distribution of organ transplantation services is that our national image and moral reputation can be adversely affected if excessive rates are charged for organ grafts in wealthy foreign nationals. Information on this point is extremely difficult to obtain. It does seem to be the case, however, that some surgical services charge differential rates so as to receive additional payments from non-resident aliens for kidney transplants. Reportedly, some surgical services charge wealthy non-resident aliens up to five times as much as they charge Americans, or even more.

Before any federal or even non-federal medical policies are established in this area, we need additional information that can best be gathered by a representative and highly competent national commission for the study of international aspects of organ transplantation.

The following has been offered as justification for a higher rate charged to patients from wealthy nations that do not have sufficient transplant service of their own: The people from that country did not contribute through payment of taxes or in other ways to the costs of research and development of the technology that makes it possible for U.S. institutions to do extensive dialysis and transplant services. U.S. institutions and tax-payers did make this development possible. Consequently, it is justifiable to charge foreign nationals more than we charge U.S. citizens and residents.

A serious moral objection against the differential fees is simply that the practice corrupts a profession that should be and is by its very commitment or promise a profession in the service of the welfare of others, a dedication to which pecuniary considerations are secondary. Furthermore, it would be unjust to appropriate for private gain medical fees that are intended for public reimbursement.

If the proposed legislation (H.R. 4080) were enacted and put into effect, the federal government might run a great risk of becoming a party to excessive profits by underwriting expenses for an efficient organ-procurement system. I urge that the federal government, if it takes steps comparable to those proposed in H.R. 4080, make adequate assurances that there will be a uniform fee for organ transplant services. Such assurances should not exclude the possibility of a patient knowingly and willingly paying more so as to directly offset costs for the poor who equally need the life-saving service but who cannot afford it.

2. Fees for Preferential Service

An additional ethical question is raised by the allegations that wealthy non-resident aliens have bought their way to the top of the transplant list and in so doing have displaced Americans. Any depiction of aliens depriving Americans of life-saving organs that were "made in America" has the inherent potential for arousing deep-seated resentment. But there is an added edge of moral impropriety if a fellow American physician or hospital has been enriched in the process of the favoritism that seems to cost the American his or her life.

One may find that justification of this practice, wherever it may exist, is argued in terms of the opportunity it presents to off-set the fixed costs of operating a transplant service or even an entire hospital. Whether an argument of that sort could outweigh strong objections in terms of greedy practices and neglected responsibilities is doubtful.

Furthermore, in such a case, it would be morally unjustifiable professional behavior if a surgeon led a patient to believe that he or she should stand by for the next available, medically suitable organ, but then not get back to the patient, because in the meantime the surgeon found a foreign national who would pay more for the organ that was suitable for the first patient. It is wrong because of the element of moral abandonment entailed in failing to provide a medical service in conditions that do not relieve the professional of his or her responsibilities. Such an action could also be a breach of promise, if there had been an agreement that these medical services would be provided to the first patient. (I am speaking here of moral standards that are internal to the physician-patient relationship. I make no judgment on what sort of external action could be taken on this conduct in the public forum, in terms of legal liability.)

The prospect of fees for preferential services, whereby Americans might be greatly enriched by aliens seeking our medical technology, raises issues of a more general sort related to fee structures and the alien. The proposed legislation (H.R. 4080) would apply federal funds to the procurement and distribution of organs that would then be transplanted in aliens on a fee-for-service basis. Increasingly, American surgical and medical services are delivered in the context of for-profit corporations and other institutions. My concern is that federal legislation intended to improve the availability of organs should not become a device for strengthening an American market monopoly on organ transplantation in a global dimension.

Consequently, I urge that any federal legislation designed to facilitate the procurement and distribution of organs for surgical transplant be linked with an international program of medical cooperation, in which knowledge and experience will be shared, international research projects be undertaken, and the skills for transplant services be shared with those of other countries.

3. Allocation of Kidneys from the (U.S.) ESRD Program to Aliens who are Already Patients

It is difficult to obtain reliable and comprehensive information on the extent to which aliens, either overseas or in this country, make use of kidneys that have been acquired through the ESRD Program, and what the various hospital policies are with respect to whether aliens have equal or unequal access to those organs in comparison with the access granted to Americans.

There would probably be little or no moral objection raised by American citizens if only those organs not chosen for use by Americans are grafted into aliens in our hositals, or are shipped overseas for use by aliens. I assume that little moral objection would be raised in those cases, because there is little chance that American citizens would be harmed or slighted by such practices.

Yet one might wonder whether an "Americans first" policy is in fact so unobjectionable, in the case of aliens who have been accepted as patients in the U.S. By the "Americans first" principle, I am referring to a principle that absolutely restricts aliens to a secondary status in the matching and allocation of suitable organs: in this policy, aliens are restricted to the use only of those organs that have been rejected by Americans.

Even when one takes into account the claim that organs rejected in earlier matches with Americans will rarely have been rejected for reasons of the inferior quality of the organ, and therefore that the term "rejected" is not per se a pejorative term, it is appropriate to ask: Should this pool of rejected organs be the only one to which alien patients have access? I am suggesting that we need to discover whether restriction of aliens to that pool of organs that have been, for whatever reasons, rejected by Americans places them and their transplant surgeon under the pressure of possibly having to settle for an organ of inferior quality, or whether their options are medically less optimal than the options available to American patients who seek a matching organ.

For if the risks of inferior quality or less than optimal choice are systematically encountered by aliens in the application of the "Americans first" policy, this would be an offense against the traditional principle of ethics in medicine, that the physician (and, by extension, the hospital) should act only in the best (medical) interests of the patient. If an American physician or surgeon has accepted a foreigner as a kidney patient because of a referral from a physician in another country, medical ethics requires that the U.S. physician be "blind" to the nationality or citizenship status of his/her patient, in deciding the appropriate quality of medical care.

Thus, because of a physician's obligations to aliens, whenever there is a shortage of optimally matchable organs, a straightforward "Americans first" policy is morally objectionable. If American public policy makers want to protect this traditional ethic of medicine, as I think they should, they will have to either stimulate increased organ procurement so that the supply will always be adequate, or limit the numbers of aliens who are accepted as patients. However, as I will suggest below, our obligations to aliens does not leave us entirely free in choosing the second option, i.e., in refusing to accept aliens for medical care in this country.

4. Allocation of Lifesaving Transplants to Poor Aliens Who Are Not (Yet) Patients

We considered above the question of the allocation of organs to aliens who had already become patients of U.S. physicians. Relevant to these hearings but much more problematic is the question of our obligations to the desperate alien who, because of financial limitations, has no prospects of becoming the patient of a U.S. physician for purposes of a surgical transplant. What are the obligations of our nation, our health-care institutions, our health-care professions, and our voluntary associations towards those aliens who are not only unhealthy, but whose lives are threatened by causes that are remediable in the United States, but in relatively few other places? This is surely the most fundamental ethical question affecting the interface between our system of organ allocation and the alien. And it is a question that deeply disturbs many U.S. physicians and surgeons, though it has scarcely been discussed in any public forum.

Here we must distinguish between those who are here and those who are not (yet) here. Recently there have been cases in which desperate, poor aliens have managed to gain entry into our country, and then gained admittance to the emergency room of a hospital. Taking advantage of the legal and professional assumption that an emergency room will not turn away those who are in serious and immediate risk of losing their lives, in situations where transport to another hospital is medically prohibitive, these patients have been able to save their lives through access to expensive dialysis treatment (and other high-technology services) in spite of their inability to pay.

Responsible hospital administrators and physicians hustle to find the money somewhere to pay the bills; but in the meantime, these cases provide us with an example of an egalitarian principle whereby lives are saved without discrimination as to citizenship, but simply on the basis of their being here, of their presenting themselves in need. In the recent Plyler v. Doe case in the U.S. Supreme Court we saw a similar egalitarian principle operate in reference to non-resident, non-immigrant aliens who sought another, less urgent service: access to a free education in public schools.

What, then, are our obligations to aliens who have end-stage renal disease, are poor, and who are desperately seeking someone who will save their lives in our country? What are our obligations towards those who are not (or not yet) directly seeking access to our country for such purposes?

The question presents very far-reaching problems of political philosophy. It is my view that our Western intellectual traditions do not serve us adequately in our search for an answer to this question. For example, theories of distributive justice have generally assumed that serious, justice-related obligations in the distribution of benefits end at our national boundaries. Yet we are factually in many ways citizens of a global community: increasing and substantial international interdependencies prove that our assumptions about moral obligations ending at our borders are deeply suspect. In my view, a contemporary theory of justice and of beneficence, a theory that takes account of the nature of the global community in which we live and its many injustices and inequities, would incline toward the conclusion that we do indeed have serious moral obligations, in both social justice and beneficence, to assist those strangers or aliens who have desperate need for human organs and for organ transplant technologies.

If we were to apply the Good Samaritan principle in a way suggested by one contemporary American philosopher (Michael Walzer, "The Distribution of Membership," in Boundaries: National Autonomy and Its Limits, ed. by Peter G. Brown and Henry Shue; Totowa, N.J.: Rowman and Littlefield, 1981), the principle would help to clarify what we owe aliens in the international sphere. In this perspective, the Good Samaritan principle can be a reason for charging communities as such--countries, their component states, cities, hospitals, professional groups, etc.--with helping others, regardless of their citizenship, simply because they are in need.

The main objection to applying a Good Samaritan principle in the international sphere is the problem of limitations. Common sense--but even the Good Samaritan principle itself--says that we should assist the needy we encounter, but that the risks and costs of giving should have a reasonable limitation. The difficult task of public policy is translating the Good Samaritan principle into standards of international health assistance within reasonable limits. This would seem to call for some sort of quota system for the benefit of aliens in programs of organ procurement and distribution. This recommendation might take the following specific forms:

a. When surgeons, physicians, or hospitals experience considerablee financial enrichment by transplanting foreign nationals who are able to pay, they should seriously consider establishing a voluntary foundation, profits from which would be ear-marked for organ transplantation and organ procurement for poor foreign nationals.

b. Community hospitals, with community financial support, could provide a certain number of organ transplants for destitute aliens per year.

c. Similarly, hospital corporations could establish a policy of absorbing the risk and cost of providing a certain number of organ transplants annually for destitute aliens.

d. Similarly, I urge that the federal government make provision for a Good Samaritan quota in its programs for organ procurement and distribution, for the benefit of the destitute alien.

Thus, I see serious moral problems with an isolationist policy that would restrict our organ procurement and distribution policies to the United States. It is a question of what sort of moral character we want our nation to have. I believe that a Good Samaritan policy that closes at least one eye to national boundaries presents an appropriate moral standard for the public programs you rightly propose.

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Mr. GORE. Thank you very much.

Without objection, I would like to include in the record at this point, or right after the testimony of Dr. Ivanovich, a summary prepared by Dr. Ivanovich that shows all of the Saudi Arabian patients in the United States, at what centers, the current status, and so forth.

Dr. Ivanovich, this summary which you provided, only includes the patients that you and Uni-Med brought in; is that right?

Dr. IVANOVICH. That is correct.

Mr. GORE. And that—could you use the microphone and turn it on there?

Dr. IVANOVICH. That is correct, Mr. Chairman.

Mr. GORE. How many is the total? How many did you bring in?

Dr. IVANOVICH. There were 75 patients that were brought into the United States over a 2-year program, a 2-year period in this program.

Mr. GORE. And the total is what, 179, according to the—go ahead.

Dr. IVANOVICH. According to our own data, which I can address, I can say that there were 92 patients from Saudi Arabia on whom blood and data were sent to this country. Seventeen of those 92 were excluded from consideration for medical contraindications or high lymphocytotoxic screening. Seventy-five were accepted by 18 centers in this country, and of those 75, 40 patients were transplanted, 21 in 1982, and 19 up until September 1983.

Mr. GORE. Now, according to the Saudi Government—and we spoke with their Embassy personnel extensively prior to this hearing—according to the Saudi Government, during the years 1980 through 1983, 179 Saudis came to America for transplants, and 114 have received transplants. Those are transplants, and 114 have received transplants. Those are are 3-year figures; your figures are for 2 years.

Were you the sole source of Saudi referrals to this country during those 2 years?

Dr. IVANOVICH. Absolutely not, sir. There were other arrangements, primarily through institutions in Saudi Arabia, with specific physician-surgeons at specific U.S. centers. For example, our dealings were strictly with the Ministry of Health hospitals in Saudi Arabia. Referrals came also from the private hospitals in Saudi Arabia, they came from the Ministry of Defense hospitals, which have dialysis facilities, and I believe also there have been American companies in Saudi Arabia that have referred patients to specific centers in this country.

Mr. GORE. I see.

Well, let me say for the record that the Saudi Government has been extremely cooperative in providing all of the information that we requested related to this difficult issue.

Now, Uni-Med, the company which you served as medical director, is a private corporation; is that correct?

Dr. IVANOVICH. That is correct.

Mr. GORE. And this private corporation entered into an arrangement with the Saudi Ministry of Health; is that correct?

Dr. IVANOVICH. That is correct.

Mr. GORE. And you endeavored to place Saudi patients in American hospitals?

Dr. IVANOVICH. Yes.

Mr. GORE. OK. Now, what was the rate of reimbursement that you were working with? What was the average cost of the transplant?

Dr. IVANOVICH. I cannot give you specific figures because I did not monitor those personally. The arrangement was such so that institutions that had expressed interest in working with the acceptance of patients from Saudi Arabia were told that patients would be supplied to them for consideration, that were medically suitable for transplantation. They were to be charged the standard rates and fees that any other individual would be charged. There was to be at no time any discussion of any special prices or bonuses for the transplantation or treatment of these patients.

Mr. GORE. Are you pretty sure about that? Are you pretty sure that all of the patients that you placed were charged no higher than the rate approved by medicare?

Dr. IVANOVICH. I was asked in one case to review the charges by one institution. It was in an instance where a patient had had a complicated posttransplant course.

I had reviewed each and every charge and found nothing out of line. Those charges were from a Washington, D.C. hospital, Georgetown University Medical Center.

Mr. GORE. Let's don't get tangled in semantics here. There is—you help me to understand it clearly.

If a hospital charges $100,000—I'm picking this number out of the air—if the hospital charges $100,000, and medicare approves $75,000, and then reimburses 80 percent of that amount, then the hospital is only getting from medicare 80 percent of 75, or 60—I can't do that in my head that quickly, I'm embarrassed to say, but roughly that amount.

If a Saudi patient is paying $100,000, then the charge is the same in each case, but the money actually received is a lot more. Do you understand my point?

Dr. IVANOVICH. I understand your point very clearly.

Mr. GORE. The concern is—and we want to keep this whole thing in the proper perspective—it shouldn't be blown out of proportion but it needs to be examined carefully and sensitively. One of the issues is whether or not this financial incentive leads to an unjust change in the priority list.

Now, what I'm trying to get from you is, in your arrangements with the Saudi Government, those patients that were located here in the United States, or placed in the United States, were they effectively giving more money to the hospitals than American patients were.

Dr. IVANOVICH. In answer to your question, I do not believe that to be the case, because if there were any problems that developed during my period of time working with the program, they were social problems, and the other problem was payment problems. There have been some—I know of one specific United States institution that has refused to accept additional patients from Saudi Arabia because of difficulty in payments.

Mr. GORE. Now, do you know of any grants to American hospitals following transplant procedures by Saudis?

Dr. IVANOVICH. None to my knowledge, Mr. Chairman. And——

Mr. GORE. Well, again there is anecdotal evidence of the kind that can't be admitted or trusted, but you know of no such instance where there's been a followup request for a grant and then a grant has been forthcoming?

Dr. IVANOVICH. Not to my knowledge.

Mr. GORE. Now, what was Uni-Med's fee schedule? Did you get a percentage or a flat fee?

Dr. IVANOVICH. The corporation received a specific amount of money, I believe, on a contractual basis, and I was paid a specific amount of money for my own services.

Mr. GORE. Was it a flat fee per transplant?

Dr. IVANOVICH. No, sir. It was a fee on a yearly basis.

Mr. GORE. No, I'm talking about Uni-Med now; they got a fee on a yearly basis?

Dr. IVANOVICH. I believe so. It was a contract for 1 year and then it was renewed for a second year, and then Mr. Spencer chose not to renew it for a third year.

Mr. GORE. Now, in your discussion with the transplant centers, were they anxious, generally speaking—you gave one exception—but were they generally anxious to accept Saudis and other nonimmigrant aliens?

Dr. IVANOVICH. "Anxious" I don't think would be the term. I think they were pleased to accept. Most of them have dealt with the care of nonresident aliens in the past. They had been referral centers and centers where I knew the physicians and surgeons.

Mr. GORE. Why do you think they were, to use your word, "pleased" to do so? What motivations are there? I talked about the potential financial incentives; what others would you add to that list?

Dr. IVANOVICH. My own belief is that many of these individuals had worked with physicans from other countries. Most of these physicians and surgeons, some my fellow witnesses, have traveled to other countries and have helped perhaps to bring some of our technology to those other countries. We have accepted some of their patients and tried in that way to increase the international cooperation with those other physicians.

Mr. GORE. Now, in your statement you seem to take the position that really we ought to ignore national boundaries altogether. Is that your view—I mean, in the priority listing of transplant patients?

Dr. IVANOVICH. No, I don't mean to ignore our own patients, and I think I stated clearly that, as long as it does not jeopardize or prejudice the care of our own patients.

Mr. GORE. Do you think that Americans should be given priority? Let's suppose that a nonimmigrant alien has a slightly better match for an available organ; should the American citizen still be given priority over that nonimmigrant alien?

Dr. IVANOVICH. That is the policy at our own institution and probably what is done everywhere, although I cannot speak—I think that is a decision that must be reached by the individuals who are assessing and trying to determine which patient will most likely have a successful result with that transplant.

Mr. GORE. Well, as we'll find out later today, that is not the policy everywhere. But you think it should be?

Dr. **Ivanovich**. I think it should be considered, absolutely.

Mr. **Gore**. Well, but do you think it—I don't want to pin you down, but do you think that that should be the policy?

Dr. **Ivanovich**. That first the consideration of the success of the transplant, or that——

Mr. **Gore**. No, that Americans should be given priority, even in cases where the scientific criteria point toward a slightly better match for a nonimmigrant alien.

Dr. **Ivanovich**. Probably, yes. I would have to state that I think——

Mr. **Gore**. OK. I have several other questions, and I haven't even gotten to the other panelists. But I want to recognize my colleague, Congressman Skeen.

Mr. **Skeen**. Thank you, Mr. Chairman. I would like to continue along the same vein.

Does anyone at that table, any one of the members of the panel, have any instance where there has been an unusual differential in payment made by a foreign country? Do you have an example or do you know of any time that a payment of this kind was ever made?

No one seems to have any idea.

Let me ask Doctor——

Mr. **Gore**. Mr. Bauer, you clicked your microphone on. Do you have such knowledge?

Mr. **Bauer**. None specific, Mr. Chairman. I have heard anecdotal comments and stories, but I cannot quote you chapter and verse, no, sir.

Mr. **Gore**. In other words, patients and people waiting generally believe that to be the case, whether it is or not.

Mr. **Bauer**. It certainly is common rumor.

Mr. **Gore**. OK.

Mr. **Skeen**. I was being briefed and at the same time I was missing—would you please state that again, Mr. Bauer?

Mr. **Bauer**. Chairman Gore asked me, Mr. Skeen, if I had any specific knowledge about higher schedules of fees being paid by non-U.S. residents for these kinds of surgical services, and I told him that I did not, that there were certainly many anecdotes that I had heard, and the general belief among my fellow patients is that that is the case. But I have no specific knowledge.

Mr. **Skeen**. I know, as counsel was informing me, about the differentials and what's been picked up by medicaid and what the fees are. It's very difficult to winnow out all this.

Has there been anything, to any of you, of an unusual nature insofar as fee assessment regarding these kinds of transplants? You don't have any particular—no one apparently does.

Dr. Ivanovich, would you ask—let me ask you this question. Why did Uni-Med decide not to renew their contract?

Dr. **Ivanovich**. It represented a lot of work for what I think Mr. Spencer felt was inadequate reimbursement. I can truly say that it——

Mr. **Skeen**. So it was an opinion assessment, then?

Dr. **Ivanovich**. It was—that's a major consideration. Second, the Saudi Embassy had established a medical health office in Washington that has been able to assimilate much of the work that was done by Uni-Med and is doing a very fine job of it.

Mr. SKEEN. You state in your testimony that you don't believe there should be any—or there should not be a uniform established policy on transplants for nonresident aliens, and that the decision should be left strictly up to the physician and the administration of each specific institution.

Dr. IVANOVICH. Well, I felt that I would not wish to force the transplantation of nonresident aliens on those institutions that wished not to consider them. That was the intent of that statement.

Mr. SKEEN. I may have taken it out of context. Then it is not your belief that there should not be at least some established policy, and I get a little dichotomy here between you and some of the other members of the panel. I was very interested in that.

Dr. IVANOVICH. In that regard, if that could be addressed and considered without forcing anyone to accept someone, who did not wish to, I think there certainly could be—it could be then a matter——

Mr. SKEEN. Professor Reich, I was very interested in your comments on the legislation that we have going through the Congress, and the recommendation, too, for a policy or advisory council.

Now, would that in any way—because I know that there are so many ethical considerations to be made in this thing, and I think it's a very valuable recommendation. Do you have any idea how you would constitute such a council of this kind?

Professor REICH. Just general recommendations. I think there have been previous commissions that have been established by the Federal Government. There is the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; there was the Ethics Advisory Board of HEW, later HHS; there was the President's Commission or whatever it's called, the Study of Ethics in Medicine and Biomedical and Behavioral Research. Those commissions, I think, would serve as good models.

It includes scientific and medical people, but in a predominance. In that sense, I think I perhaps would differ from your recommendation about the constitution of the advisory council, where physicians/surgeons and those professionals who are involved in the procurement of organs do dominate——

Mr. SKEEN. You would broaden the base, then?

Professor REICH. I would broaden it somewhat, yeah. And I think those other commissions would serve as good models as regards the constitution of the commission.

Mr. SKEEN. Let me ask one final question then, Mr. Chairman, and that is, does anyone know of any displacement of any—I know there is not—I don't know what you'd call it—a priority list for donors at this time. Does anyone on this panel know of anyone who was displaced as a patient because of a nonalien or an alien transplant?

Evidently not. Oh, excuse me.

Ms. LINDSAY. As I stated in my testimony, there are instances where a patient feels like they have been passed over. But at the present system, there is no way to verify this.

Mr. **Skeen**. But there is a strong feeling among patients that they have been displaced, or that there has been some displacement?

Ms. **Lindsay**. Yes. And in some instances, they can point to a specific transplant or organ that they feel like they have been passed over.

Mr. **Gore**. Will my colleague yield?

Ms. **Lindsay**. But they cannot—there is no way to verify it at this time.

Mr. **Skeen**. Mr. Reich, I believe——

Professor **Reich**. If I understand it correctly—and I'm a little simple minded when it comes to mathematics, computers, and complex distributional questions—but aren't people being passed over all the time? Every time you make a decision about selection and distribution of an organ—when the matching comes up in a computer—people are always being passed over in favor of the one who is actually transplanted. Aliens are transplanted, and therefore, in that sense, people are always being passed over.

Wouldn't it be the case that any hospital or medical center that did not have a very strict, rigid, and absolute Americans first policy, whereby only so-called discarded organs—that is, organs that have been rejected—would go to aliens, does in fact exercise some sort of discrimination? That's my simple minded sort of a question that I——

Mr. **Skeen**. We're all kind of simple minded in that regard, Doctor. I'm not—I was just posing the question because it's a very emotional and traumatic one for people involved. And excuse me for not yielding to you——

Mr. **Gore**. Oh, no, that's fine.

Mr. **Skeen**. But let me run this out.

But I have to say that's one of the reasons we're having this hearing here today. Let's lay all this out on the table and let's see how people really feel about this question. Because I was very interested in the international aspects of your recommendations earlier, which I think is eventually what we're going to have to, because the doctor in his or her approach to this kind of a question deals with the patient as an individual, not with the system.

I think you're absolutely right. We're trying to initiate some kind of legislation, and all this bears back again on whether we've got something that's worthwhile or not. Are we going in the right direction, because meddling with the statutes causes one to pause. Of course, we jump right in in this part of the system of Government because we just love to pass all these laws and so forth, but once in a while you have got to just take a look and see are you going in the right direction, are you doing what you intend to do without creating another obstacle. I like very much the approach you have taken, and from the aspect of the physician, and the ethics involved, that we're going to have to evolve some kind of international policy. I hope that the kind of work that we're doing on this legislation could probably or may serve as a model somewhere along the line for the development of just that kind of policy.

So I would like to ask the question, though, that those who feel like they've been injured, do you have any examples and so forth, because then it helps us deal with this thing, even on the emotional level. Now that I have pontificated long enough, I'll either yield to any of you that have a response, if you do, or I will yield to the chairman.

Mr. GORE. Let me followup on your question just a moment ago with Ms. Lindsay.

We were told of a patient in ESRD Network 23 who was notified to stay near the telephone. She was about to be transplanted, or a donor with a good match had been located. She stayed by the telephone and was not contacted, and later was told that both of the kidneys from the donor went to nonimmigrant aliens.

We contacted this—well, this patient was not willing to testify publicly, but I'm told that the two of you know her. This is anecdotal information of the worst kind in one respect, but it does illustrate the fact that the patient population and those waiting for transplants believe that there is an unfairness in the current system as regards nonimmigrant aliens.

Can you shed any further light on that specific instance, Ms. Lindsay?

Ms. LINDSAY. Well, other than what I stated in my testimony, what you say is essentially——

Mr. GORE. Could you bend that microphone down and turn it on?

Ms. LINDSAY. What you say is essentially true. The patient did not wish to testify, because as I stated earlier, there is a genuine fear among the patient community about identifying themselves, because it has been rumored that at times the matching criteria has been changed when a patient has been difficult or uncooperative. So they tend to shy away from identifying themselves.

This particular patient, as you stated, was told to stand by and wait for a kidney. There were two kidneys available from the same accident victim. Both kidneys went to nonimmigrant aliens. The present system——

Mr. GORE. What hospital was that?

Ms. LINDSAY. I would prefer not to identify——

Mr. GORE. Well, we're going to have the people from—It was Washington Hospital Center, was it not—I mean, we're going to have people from there——

Ms. LINDSAY. No comment.

Mr. GORE. OK. But we have asked them to bring the records of that specific case, and we're going to review whether or not that was, in fact, the case.

Ms. LINDSAY. The problem is not whether that kidney was correctly transplanted. The problem is there is no way of determining it. It may have been the best match for the persons who received it.

Mr. GORE. Well, there is a way to determine, because we can look at the criteria, both with respect to the woman who was notified to be near the phone, and the two nonimmigrant alien patients, and see in fact whether that was a medical decision or whether it was another kind of decision. I think the results may be interesting.

Ms. LINDSAY. Well, I think that this very incident just seems to emphasize the point that the system of designating organs has to be better defined, so that there is no potential for abuse. I'm not saying that there was. I'm just saying there is just a very tenuous area.

Mr. GORE. OK.

Did you have other questions?

Mr. SKEEN. I just have an observation, Mr. Chairman. It goes back now to whose responsibility is this to make the final determination. I can see that—I don't know if you could ever craft into legislation the kind of law that would give you an absolute certainty, that you would have some kind of a system that would be totally equitable and fair, because it still remains in the hands of the physician, or the determination has to be made there. I think it goes back to the question I asked Dr. Ivanovich and then Dr. Reich, so it's a very serious one.

I know, too, that many times there are other extenuations that again—I mean, it's a judgmental question for the physician and physician alone. A person who is a donor, or is a prospective recipient, will turn up with a cold 2 days prior to the thing and that knocks them out of the whole run until they clear all that up. Those kinds of things are very difficult to—and again very emotional in all their judgments. If you have to go case by case, we're going to be here for an awful long time.

But thank you very much, Mr. Chairman.

Mr. GORE. Dr. Ivanovich, a few more questions.

Do the Saudis remain on the waiting list longer than others, on average, or a shorter time, average length of time? How would you estimate it from your experience?

Dr. IVANOVICH. I can't answer that question exactly. I would imagine that they stayed on an average length of time as the others at those centers. I think some of the other witnesses to appear here today are at those centers and perhaps they could better answer that question.

Mr. GORE. Now, are the Saudis now developing their own program for transplantation?

Dr. IVANOVICH. Yes, they are, Chairman Gore.

Mr. GORE. We had indications earlier that there were religious and cultural barriers to a transplantation, but in fact those are changing somewhat, are they not?

Dr. IVANOVICH. Somewhat, at least. There is limited related donor transplantation——

Mr. GORE. But no cadaveric donor transplants?

Dr. IVANOVICH. There is an American surgeon, transplant surgeon, who is working very diligently in Saudi Arabia trying to change those conditions. But it may take some time.

Mr. GORE. I can barely imagine how difficult and sensitive a problem that is. But presumably all ethical systems have the ability to adapt to near realities when compassion and the opportunity to save lives is at stake.

Now, you told us, Professor Reich, about the problem of illegal aliens or—let me back up. You used the phrase poor aliens, low-income aliens, somehow getting into the United States and placing themselves at an emergency room.

Do you have specific examples of that kind of problem?

Professor REICH. Yes, I know of at least one case where that happened.

Mr. GORE. From what country?

Professor REICH. The person came from Haiti, a desperately ill person, for whom there was no such medical service in their country, no dialysis.

Mr. GORE. Came into the country illegally?

Professor REICH. I'm not sure if it was illegally, but—I'm not sure. It may have been with a visitor's visa, but not with immigrant status or with a——

Mr. GORE. Is this person still in a U.S. medical center?

Professor REICH. No, no.

Mr. GORE. Was this person transplanted?

Professor REICH. To my knowledge, I think perhaps she's waiting for an opportunity to be transplanted. She's being dialyzed on an outpatient basis.

Mr. GORE. In the Washington area?

Professor REICH. Yes.

Mr. GORE. We were advised of another similar case of an immigrant from Pakistan who came on a tourist visa and showed up at a center in Maryland, and has had two transplants, paid for by the State of Maryland, owes $106,000, and is now awaiting a third transplant, and was also on a number of Federal programs at the same time that paid for part of that.

Now, I'm given to believe that this policy of Americans first is used by a number of centers, probably the majority of centers, but not by all. Dr. Ivanovich said a moment ago that he feels that probably is the policy we should follow nationwide.

Professor Reich, you're not so sure, are you?

Professor REICH. No, I'm not so sure at all that that should be used as an absolute standard. I do think we have some obligations—we could call them prior obligations—toward our fellow citizens. But the idea that medical service and care, compassionate concern for and service to the truly desperately needy should end at our national boundaries, I think is an archaic, immoral notion that should not have a place in our system as an absolute standard.

Mr. GORE. But we do have what you referred to as prior obligations to our own citizens; that's not archaic?

Professor REICH. No. It's a very, very difficult question of political philosophy that has plagued political philosophers and politicians for most of the recorded history of mankind, especially in modern political philosophy. How do you on the one hand explain and justify and carry out a policy of a legitimate national self-interest, caring for one's own fellow citizens, without slipping into an attitude simply of bigotry—that is to say, blindly closing our eyes to the needs beyond our borders? It seems to me that in our systems, our philosophical systems of justice, as well as in some of our political theories, we have acted sort of on a notion of national autonomy—our services, our goods, produced here for our people—and only if there is a surplus, and only as a matter of altruism, do we help others. I think that's just not sustainable any more, partly on a factual basis.

The world has become a very strongly intertwined, interdependent community in many respects, and I think our assumptions about justice have to accommodate that, and I think our policies, including our health policies, have to accommodate that.

Mr. Gore. Well, let me ask you a specific question. Let's say you've got an organ available for transplantation, and you've got two patients, one of them an American, one of them a nonimmigrant alien. The medical factors are fairly close. There will be an acceptable match for either patient, but the odds of success are slightly higher with the case of the nonimmigrant alien.

Would you give priority in that case to the American patient——

Professor Reich. It depends on——

Mr. Gore [continuing]. If they're at the same institution, there are no geographic factors involved?

Professor Reich. It depends on the moral responsibilities that are involved in the case, partly. Your question is framed in such a way that you're asking for a sort of principle that would guide medical policy, perhaps also national policy. But in addition to principles, there are such things as responsibilities. If both of these people are, as you say, patients at the same institution, then there is a factor there of professional responsibilities and institutional responsibilities to them as patients. So in the case that you describe, the question that you ask, I would say that no discrimination should be made on the basis of country of origin and that the decision has to be made in a fully equal way on medical grounds—in the case that you present.

Now, quite different——

Mr. Gore. What about the responsibility of the medical professionals in that institution to sustain the rate of voluntary donation in our country, and what about the problem that when people find out about nonimmigrant aliens getting a disproportionate percentage of available organs, then you get a decline in the rate of voluntary donations? Should that be taken into account as an ethical factor?

Professor Reich. Yes, it should be taken into account. But I happen to be of the opinion that the whole question should be turned around the other way. It's understandable that you and Mr. Skeen want to know do people feel as though they have been offended by being displaced by aliens. But when you ask the question whether serving aliens or giving them some priority, or equal access, would diminish the voluntary donations in this country, I think the question should be turned around the other way; that the medical community—and that is the way you asked the question—that the medical community should use realistic and positive motivations toward fostering voluntary donations among those ethnic groups and national groups that are represented among the pool of aliens who are served.

For example, if a hospital, or in a given region if a number of hospitals are serving Greeks, Arabs, northern Europeans, Asians, or whatever, it seems to me that a creative program touching upon voluntary organizations, churches, ethnic groups, and so forth, could make a strong appeal to an increase of voluntary donations of organs precisely because of their fellow conationals who are citizens of other countries and who might benefit from this. So it could be turned around, it seems to me, to increase the pool of organs available.

Mr. Gore. Well, that's a sentiment I would share. I just don't think it's likely to accomplish very much. There is some evidence that the Greek community has, in fact, had some result. But generally speaking, the populations involved are small and it doesn't have much effect. I'll stand corrected if you wish to add a statement for the record on that.

Professor REICH. I'm not sure if it's really been tried very vigorously, that's what I'm not sure of.

Mr. GORE. Before going on to our next panel, let me just follow up on loose ends here.

Ms. Lindsay, in your comments you indicated that there is a fear on the part of patients related to the power that is held over their lives, and a real reluctance to get very active in challenging the way some of these decisions are made; is that correct?

Ms. LINDSAY. Correct.

Mr. GORE. It must be tough waiting for a transplant and having that kind of fear. It must be hard to be chained to the telephone as well during that stage.

Is that a common experience?

Ms. LINDSAY. I understand a number of patients who are waiting for transplants get beepers, so that they can lead a fairly normal life as far as leaving the telephone——

Mr. GORE. Those who can afford them.

Ms. LINDSAY. Those who can afford a beeper, right.

Mr. GORE. Well, let me——

Ms. LINDSAY. Can I make a comment about the encouraging of different ethnic groups? For what it's worth, I understand that even here in America there is a great discrepancy between the races as far as their willingness, for whatever religion or philosophical reason, in donating organs. Dr. Calendar at Howard University had stated that black recipients most often receive kidneys from white donors, simply because the black community has not kept pace with the idea of organ donations; therefore, there just are not as many—not that it should make any difference one way or the other, except that it does indicate that in ethnic groups perhaps, and racial groups also, don't necessarily donate as willingly, depending on their group.

Mr. GORE. Well, the figures certainly bear that out, and there is much work to be done in convincing all Americans to be more willing to make organs available for donation. The numbers in the black community need to be lifted proportionately.

Ms. LINDSAY. Right.

Mr. SKEEN. Mr. Chairman, if I might ask, is the ethnicity question any real—have any real medical basis for making matches that are of less risk, or involve less risk, things of that kind? It's a curious question.

Mr. GORE. We're going to receive some testimony on that from the next panel. A brief answer is that the distribution of blood types is different according to ethnic background, and that has affected this issue significantly.

Let me thank all of the members of this panel. We appreciate your participation very much. Thank you.

Mr. BAUER. Thank you, Mr. Chairman.

Mr. GORE. I would like to call our second panel to discuss in some detail the priority systems for organ allocation and how they are constructed. Dr. Nicholas Feduska, chairman of the Committee on Organ Sharing and preservation for the American Society of Transplant Surgeons; Amy Peele, president of the North American Transplant Coordinators Organization; Dr. John McDonald, president of the Southeast Organ Procurement Foundation; Dr. Paul Terasaki, director of the Southern California Regional Organ Procurement Agency; and Dr. Henry Krakauer, with the National Institutes of Health, Institute on Allergy and Infectious Diseases, in Bethesda.

Lady and gentlemen, if you would stand and raise your right hand, please. Do any of you have objections to being sworn?

Do you solemnly swear the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses respond affirmatively.]

Thank you very much.

I have introduced all five of you in calling you to the witness table. I would like to thank all of you for your presence here today, and without objection, your complete statements will be included in the record at this point. If you care to summarize any portion of your statements, please feel free to do so. We would like to keep each of the statements at 10 minutes, if possible.

We would like to begin with Dr. Nicholas Feduska, chairman of the committee on organ procurement and sharing, with the American Society of Transplant Surgeons. And, Dr. Feduska, let me say at the beginning of your statement that we have certainly appreciated the fine cooperation and excellent working relationship that our subcommittee has had with your organization, with Dr. Salvatierra who is going to be testifying Wednesday, and we're delighted to have you here. Please proceed.

STATEMENTS OF NICHOLAS J. FEDUSKA, M.D., CHAIRMAN, COMMITTEE ON ORGAN SHARING AND PRESERVATION, AMERICAN SOCIETY OF TRANSPLANT SURGEONS; AMY S. PEELE, PRESIDENT, NORTH AMERICAN TRANSPLANT COORDINATORS ORGANIZATION; JOHN C. McDONALD, M.D., PRESIDENT, SOUTH-EASTERN ORGAN PROCUREMENT FOUNDATION; PAUL I. TERASAKI, M.D., DIRECTOR, SOUTHERN CALIFORNIA REGIONAL ORGAN PROCUREMENT AGENCY; AND HENRY KRAKAUER, M.D., NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH

Dr. **Feduska**. Thank you very much, Mr. Gore.

Mr. Chairman, Mr. Skeen, members of the committee, ladies and gentlemen. I am Dr. Nicholas J. Feduska, associate professor of surgery and transplant surgeon at the University of California, San Francisco. I am also chairman of the committee on organ sharing and preservation, of the American Society of Transplant Surgeons. The testimony I will give relates to our experience with kidney transplants performed for nonresident aliens at the University of California, San Francisco.

I will also present the results of a questionnaire which we recently sent to all of the members of the American Society of Transplant Surgeons, who represent almost all of the transplant surgeons in the United States. I hope that the information will be of interest to you and the members of your committee, and I wish to thank you for the opportunity to take part in this hearing.

Two thousand and sixty-nine kidney transplants have now been performed at the University of California, San Francisco, between January 8, 1964, and November 1, 1983. This experience is the largest of any single center in the world and includes 1,377 transplants donated by cadaver doners, 673 donated by living relatives, and 19 transplants donated by living unrelated individuals. The number of transplants performed in our center in 1981 was 160, including 1 related—that is, 0.6 percent—and 2 cadaver transplants—that is, 1.3 percent—for nonresident aliens. During 1982, 165 transplants were performed, including 1 related, 0.6 percent, and 4 cadaver transplants, 2.4 percent, for nonresident alien recipients. Between January 1 and June 30 of this year, 99 transplants were carried out, including 1 related, 1 percent, and 4 cadaver transplants, 4 percent, for nonresident aliens.

It is our policy to accept nonresident aliens as candidates for transplants if they are found to be medically suitable and reside in a country and location where they will have available to them acceptable followup medical care. In addition, they must demonstrate their capacity to deal with the complicated logistical factors involved, such as arranging and paying for travel to and from the United States as well as living accommodations while they are temporarily residing here. It is imperative that they present evidence of their ability to pay for all of the anticipated medical expenses.

You have asked that I comment about whether nonresident alien patients are actively recruited to receive kidney transplants. In our center we do not actively recruit any patients to receive transplants, U.S. citizens or otherwise, and I am aware of no transplant center in this country where such a practice prevails.

Mr. **Gore**. Excuse me. Let me interrupt you at that point.

We will put into the record, at a later point, a brochure that seems to constitute such solicitation. But I think it's probably more appropriate for me to come back to that in questions. But go ahead.

Dr. **Feduska**. We do encourage that patients who choose to receive transplants make every effort to receive a related transplant preferentially, as the success rate for related transplants is higher than that associated with cadaver transplants. However, it has been our experience that only a small proportion of patients who are nonresident aliens have a relative who is willing and suitable to serve as the transplant donor. Hence, most candidates must await the availability of a cadaver kidney from a compatible donor, and the period of waiting is entirely unpredictable and often very long.

In the case of some patients, the period of waiting may even be indefinite, particularly if their immunologic status makes it difficult to find a compatible donor. With these considerations in mind, it is our policy to consider nonresident aliens for available cadaver kidney transplants only after giving first priority to all patients who are U.S. citizens and who are awaiting such transplants in our center.

Our candidate waiting list for cadaver transplants presently numbers 454 patients, of whom 14, or 3.1 percent, represent non-resident aliens. Patients are selected for available transplants primarily on the basis of blood type compatibility, histocompatibility, and a history of previous blood transfusions. However, other factors are also considered, including current medical status, degree of sensitization, age, response to dialysis therapy, compliance, and time on the waiting list. In essence, the patients who are ultimately selected represent those who possess the features which are most likely to positively influence the chance of a successful outcome.

In spite of the large number of candidates on our waiting list, consideration of these multiple factors during the process of selection frequently results in the identification of only a small number of patients who are optimally suited to receive the transplants. It is in such circumstances that nonresident alien patients have a greater possibility of being selected.

The referral of nonresident aliens to our center is usually made by a physician primarily responsible for the patient's care in their native country. But in some cases patients refer themselves. We do not have an established referral agreement with any foreign government. On some occasions we have been contacted and asked to provide care to nonresident aliens by Members of Congress, representatives of the State Department or National Institutes of Health, and in addition, some foreign governmental agencies and authorities as well.

Foreign patients are never placed at the head of the transplant list. In fact, the waiting list has no top and no bottom. All patients are considered equally, except for those factors which I have already alluded to.

It is the practice in our center to use all suitable cadaver kidneys as transplants for patients on our own waiting list. In addition, all cadaver kidneys to be transplanted in our center are recovered from the donors with the personal involvement of members of our own specialized surgical team. It is unusual for suitable kidneys not to be utilized because of the unavailability of suitable recipients. We do not send kidneys to transplant centers outside of the United States, as we are almost always able to use available kidneys for patients on our own waiting list.

It is not our practice to charge differential rates to nonresident aliens as compared to patients who are U.S. citizens. Rather, the charges associated with organ acquisition, dialysis therapy, hospitalizations and transplantation surgery are the same.

I do not know the details of the practice in other countries relating to the allocation of organs for transplantation, or the transplantation of nonresident nationals. I would like to emphasize, however, that the United States has clearly been the leader in kidney transplantation in the world and the results which are reported from most of our own transplant centers are highly respected by transplant specialists in all other countries. I suspect that the number of nonresident aliens seeking transplants in other countries is very small.

I would now like to discuss the results of the questionnaire which I mentioned earlier. This questionnaire was sent to almost all transplant surgeons in the United States and was designed to identify the proportion of both related and cadaver kidney transplants performed in 1982 which involved nonresident alien recipients.

When possible, the native countries represented by these patients were also identified. The proportion of nonresident aliens on transplant waiting lists at the various U.S. centers in 1982 was also calculated. In addition, the questionnaire was used to evaluate if U.S. citizens are given priority for available transplants.

A completed response to the questionnaire was received from 82 different transplant centers. The total number of transplants represented by these centers was 4,030, or 75.2 percent, of the 5,358 transplants that are known to have taken place in the United States in 1982, according to data from the Health Care Finance Administration. One hundred forty-two involved nonresident aliens as recipients. Twenty-five, that is, 17.6 percent, of the nonresident alien transplants involved related donors, while 117, or 82.4 percent, came from cadaver donors.

In the case of related transplants, a wide range of native countries were represented and no country was associated with more than three transplants, as can be seen in table 1 of the material which I have provided.

Among the cadaver transplants, 30 different native countries were identified, and these are listed in table 2. The largest number of recipients were from Saudi Arabia, 39 patients, and Greece, 16 patients. The 25 related transplants accounted for only 0.6 percent of the total number of transplants performed among the 82 centers during 1982, and the 117 cadaver transplants represented only 2.9 percent of the total. Hence, a mere 3.5 percent of the 4,030 transplants involved nonresident alien recipients.

Analysis of the data from the six largest U.S. transplant centers also showed the number of related transplants involving nonresident aliens to be small, representing no more than 1.4 percent of the total number of transplants in any of these centers, as noted in table 3.

The number of cadaver transplants performed for nonresident aliens in these six largest centers was greater, but in only one center did the proportion exceed 5 percent of the total. Analysis of the proportion of nonresident aliens on the waiting lists of the six largest centers in 1982 showed that they accounted for 10 percent or less of the total number of patients waiting. Similar data were calculated for the eight transplant centers which performed five or more nonresident alien transplants in 1982, as indicated in table 4. The maximum number of related nonresident alien transplants performed in any of these latter centers was two; but the eight centers accounted for five of the total 25, or 20 percent, of the related transplants performed.

The number of cadaver nonresident alien transplants ranged from 5 to 13 and accounted for between 2.4 percent and 38.8 percent of the total number of transplants performed in the respective centers. The 58 cadaver transplants among the 8 centers accounted for 50 percent of the total 117 cadaver transplants in nonresident alien recipients, indicating that a few centers perform most of the nonresident alien cadaver transplants.

This observation is further supported by the data relating to the 1982 waiting lists for these same eight centers, which show that in the case of four, the proportion of nonresident aliens on the waiting list was 10 percent or higher.

In response to the question "Are U.S. citizens at your center given priority for available cadaver transplants?", 70 of the 82, or 85.4 percent, of the responding centers answered affirmatively. The 12 remaining centers indicated that they either give equal consideration to foreign patients, or that foreign patients are so infrequent that this has not yet been an issue. None of the 82 centers gives priority consideration to nonresident aliens.

I do not believe that there should be the establishment of a uniform policy on transplantation of nonresident aliens. The proportion of kidney transplants involving such patients is small, although in the case of a few centers the proportion is higher. A partial explanation for this observation may relate to the geographic location of some centers, as they were occasionally located in the same metropolitan area. In the case of other centers, international reputation is undoubtedly responsible for attracting the referral of foreign patients. The probability is that many of the cadaver kidneys utilized for nonresident aliens would have been discarded otherwise. It is my opinion that providing these kidneys as transplants to nonresident alien patients was a preferable alternatives.

Further, those of us who have had the opportunity to perform such transplants and care for such patients also have the impression that in doing so we are further enhancing the reputation of our country and the specialty of transplantation as practiced in the United States.

The ultimate answer to the issue of whether foreign patients should receive cadaver kidney transplants performed in the United States, utilizing kidneys from deceased U.S. citizens, will be for us to assist in improving the quality of medical care and the development of effective cadaver organ donor programs in other countries. Transplant surgeons in this country have already contributed substantially to such efforts, both in hosting foreign surgeons and other transplant specialists, as well as in teaching abroad. We are most willing to provide further assistance in the future.

I wish to thank you again for the opportunity of presenting this testimony.

[The prepared statement of Dr. Feduska follows:]

TESTIMONY BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT, COMMITTEE ON SCIENCE AND TECHNOLOGY, U.S. HOUSE OF REPRESENTATIVES, WASHINGTON, D.C., NOVEMBER 7, 1983

NICHOLAS J. FEDUSKA, M.D., ASSOCIATE PROFESSOR OF SURGERY AND TRANSPLANT SURGEON—DEPARTMENT OF SURGERY, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO; CHAIRMAN, COMMITTEE ON ORGAN SHARING AND PRESERVATION OF THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Mr. Chairman, I am Dr. Nicholas J. Feduska, Associate Professor of Surgery and transplant surgeon at the University of California, San Francisco. I am also chairman of the Committee on Organ Sharing and Preservation of the American Society of Transplant Surgeons. The testimony I will give responds to the questions that you have posed earlier, and relates to our experience with kidney transplants performed for non-resident aliens at the University of California, San Francisco. I will also present the results of a questionnaire which we recently sent to all of the members of the American Society of Transplant Surgeons, who represent almost all of the transplant surgeons in the United States. A response to this questionnaire was received from 82 different kidney transplant centers. We were prompted to prepare the questionnaire in anticipation of your interest, as well as to collect data that would make it possible to respond objectively to questions and allegations which have recently appeared in the public media and which dealt with kidney transplants performed for nonresident aliens. I hope that the information I present will be of interest and helpful to you and the members of your Committee, and I wish to thank you for the opportunity to take part in this hearing.

Two thousand and sixty-nine kidney transplants have been performed at the University of California, San Francisco between January 8, 1964 and November 1, 1983. This experience is the largest of any single center, and includes 1,377 (67 percent) transplants donated by cadaver donors, and 673 (32.5 percent) transplants donated by living relatives. Nineteen (0.5 percent) of the transplants were donated by living, unrelated individuals and all but one of these took place more than ten years ago. The number of transplants performed in our center in 1981 was 160, including one related (0.6 percent) and two cadaver transplants (1.3 percent) performed for nonresident aliens. During 1982, 165 transplants were performed, including one related (0.6 percent) and four cadaver transplants (2.4 percent) for non-resident alien recipients. Between January 1 and June 30, 1983 99 transplants were carried out, including one related (1 percent) and four cadaver transplants (4 percent) performed for non-resident aliens.

It is our policy to accept non-resident aliens as candidates for either related or cadaver transplants if they are found to be medically suitable and reside in a country and location where they will have acceptable follow-up medical care available to them. In addition, before being accepted as a transplant candidate they must demonstrate their capacity to deal with the complicated logistical factors involved, such as arranging and paying for travel to and from the United States as well as living accommodations while they are temporarily residing here. It is imperative that they present evidence of their ability to pay for all of the anticipated medical expenses.

You have asked that I comment about whether non-resident alien patients are actively recruited to receive kidney transplants. In our center we do not actively recruit any patients to receive transplants, U.S. citizens or otherwise, and I am aware of no transplant center in the United States where such a practice prevails. We do encourage that patients who choose to receive transplants make every effort to receive a related transplant preferentially, as the success rate for related transplants is higher than that associated with cadaver transplants. However, it has been our experience that fewer than 50 percent of patients who are U.S. citizens and only a small proportion of patients who are non-resident aliens have a relative who is willing, medically suitable, and immunologically suitable to serve as the transplant donor. Hence most transplant candidates must await the availability of a cadaver kidney from a compatible donor. The period of waiting is entirely unpredictable and is often very long. In the case of some patients the waiting period may even be indefinite, particularly if their immunologic status (high antibody levels) makes it difficult to find a compatible donor. With all of these considerations in mind, it is our policy at the University of California, San Francisco to consider non-resident aliens for available cadaver kidney transplants only after giving first priority to all patients who are U.S. citizens and who are awaiting such transplants in our center.

Our candidate waiting list for cadaver transplants presently consists of 454 patients, of whom 14 (3.1 percent) represent non-resident aliens. Patients are selected for available transplants primarily on the basis of blood type compatibility, histocompatibility, and a history of previous blood transfusions. However, other factors are also considered including the current medical status, degree of sensitization (antibody levels), age, response to dialysis therapy, compliance, and time on the waiting list. In essence, the patients who are ultimately selected for available transplants represent those who possess the features which are most likely to positively influence the chance of a successful outcome. In spite of the large number of candidates on our waiting list, consideration of these multiple factors during the process of selection frequently results in the identification of only a small number of patients who are optimally suited to receive the transplants. It is in such circumstances that non-resident alien patients have a greater possibility of being selected.

The referral of non-resident aliens to our center for consideration of transplantation is usually made by the physician primarily responsible for the patient's care in their native country. In some cases patients refer themselves. We do not have an established referral agreement with any foreign government. On some occasions we have been contacted and asked to provide care to non-resident aliens by members of Congress, representatives of the State Department or National Institutes of Health, and some foreign governmental agencies and authorities as well. A number of transplants have involved recipients who were migrant farm workers, and who could not be effectively treated with chronic dialysis. In any event we have always given priority consideration to patients who are U.S. citizens. In response to the other question you posed, foreign patients are never placed at the head of the transplant list.

In fact, the waiting list has no top and no bottom. All patients are considered equally except for those factors I have already alluded to.

I would like to mention that in the case of cadaver kidneys, methods of preservation have been developed which make it possible to perform the transplants as late as 72 hours (and perhaps longer) after the kidneys have been removed from the donor. Considering this fact and the amount of time usually required to complete tissue typing studies and the selection process, it is feasible to offer the opportunity of a transplant to patients who are still residing in their native country, and for the patients to fly to the United States and arrive in ample time for the transplant to be carried out.

It is the practice in our center to use all suitable cadaver kidneys as transplants for patients on our own waiting list. In addition, all cadaver kidneys to be transplanted in our center are recovered from the donors with personal involvement of members of our own specialized surgical team. Consequently the rate of utilization of potentially transplantable kidneys has been high, and in recent years had been approximately 85 percent. It is unusual for suitable kidneys not to be utilized because of the unavailability of suitable recipients. Most of the kidneys which are not transplanted are unsuitable for medical or technical reasons. We do not routinely send kidneys to transplant centers within or outside the United States, as we are almost always able to use available kidneys for patients on our own waiting list.

In response to another of the questions which you posed, it is not the practice in our center to charge differential rates to non-resident aliens as compared to patients who are U.S. citizens. Rather, the charges associated with organ acquisition, dialysis therapy, hospitalizations and transplantation surgery are the same charges as assumed by patients who are U.S. Citizens.

I do not know the details of the practice in other countries relating to the allocation of organs for transplantation, or the transplantation of non-resident nationals. I would like to emphasize, however, that the United States has clearly been the leader in kidney transplantation in the world, and the results which are reported from most of our own transplant centers are highly respected by transplant specialists in all other countries. I suspect that the number of non-resident aliens seeking transplants in other countries is very small, and undoubtedly much smaller than we have observed in our own co[illegible]

I would now like to [illegible] results of the questionnaire which I mentioned earlier. This questionnai[illegible]ent to almost all transplant surgeons in the United States, and was designed [illegible] identify the proportion of both related and cadaver kidney transplants performed in 1982 which involved non-resident alien recipients. When possible the native countries represented by these patients were identified. The proportion of non-resident aliens on transplant waiting lists at the various U.S. centers in 1982 was calculated. The questionnaire was also used to evaluate if U.S. citizens are given priority for available transplants. Finally, each of the transplant surgeons was asked to express his or her opinion regarding whether the American Society of Transplant Surgeons should take a strong public position against the buying and selling of kidneys from living, unrelated donors.

A completed response to the questionnaire was received from 82 different transplant centers. The total number of transplants represented by these centers was 4,030, or 75.2 percent of the 5,358 that are known to have taken place in the United States in 1982 according to data from the Health Care Finance Administration. One hundred forty-two of the transplants involved non-resident aliens as recipients. Twenty-five (17.6 percent) of the non-resident alien transplants involved related donors, and 117 (82.4 percent) came from cadaver donors. In the case of recipients of the non-recipient alien related transplants, a wide range of native countries were represented, and no country was associated with more than three transplants (Table 1). Among the non-resident alien cadaver transplants, 30 native countries were specifically identified (Table 2). The largest number of recipients were from Saudia Arabia (39) and Greece (16), but as in the case of the related transplants a wide spectrum of countries was represented. The 25 related transplants involving non-resident alien recipients accounted for only 0.6 percent of the total number of transplants performed in the 82 centers during 1982, and the 117 cadaver transplants to non-resident aliens represented only 2.9 percent of the total number. Hence a mere 3.5 percent of the 4,030 transplants involved non-resident alien recipients. Analysis of the data from the six largest U.S. transplant centers also showed the number of related transplants involving non-resident aliens to be small, representing no more than 1.4 percent of the total number of transplants in any of these centers (Table 3). The number of cadaver transplants performed for non-resident aliens in these six centers was greater than the number of related transplants, but in only one center did the proportion of non-resident alien cadaver transplants exceed 5 percent of the total number of transplants performed. Analysis of the proportion of non-resident aliens on the waiting lists of these six largest centers in 1982 showed that they accounted for 10 percent or less of the total number of patients waiting. Similar data were calculated and analyzed for the eight transplant centers which performed five or more non-resident alien transplants in 1982 (Table 4). The maximum number of related non-resident alien transplants performed in any of these latter centers was two, but the 8 centers accounted for 5 of the 25 (20 percent of the related transplants performed). The number of cadaver non-resident alien transplants among these 8 centers ranged from 5 to 13, and accounted for between 2.4 percent and 38.8 percent of the total number of transplants performed in the respective centers. The 58 cadaver transplants among the 8 centers accounted for 50 percent of the total 117 cadaver transplants in non-resident alien recipients, indicating that a few centers perform most of the non-resident alien cadaver transplants. This observation is supported by the data relating to the 1982 waiting lists for these same eight centers, which show that in the case of four of the centers the proportion of non-resident aliens on the waiting list was 10 percent or higher.

In response to the question "Are U.S. citizens at your center given priority for available cadaver transplants?", 70 of the 82 (85.4 percent) responding centers answered affirmatively. The twelve remaining centers indicated that they either give equal consideration to foreign patients (11) or that foreign patients are so infrequent in their center that this has not yet been an issue (1). None of the 82 centers which responded to the questionnaire gives priority consideration to non-resident aliens for available cadaver transplants.

A transplant surgeon representative for all but one of the 82 centers (98.8 percent) expressed the opinion that the American Society of Transplant Surgeons should take a strong public position against the buying and selling of kidneys from living, unrelated donors.

I do not believe that there should be the establishment of a uniform policy on transplantation of non-resident aliens. The proportion of kidney transplants in the United States involving such patients is small, although in the case of a few centers the proportion is higher. A partial explanation for this observation may relate to the geographic location of some centers, as they were occasionally located in the same metropolitan area. In the case of other centers international reputation is undoubtedly responsible for attracting the referral of foreign patients. The probability is that many of the cadaver kidneys utilized for non-resident aliens would have been discarded otherwise. It is my opinion that providing these kidneys as transplants to non-resident alien patients was a preferable alternative. Those of us who have had the opportunity to perform such transplants also have the impression that in doing so we are further enhancing the reputation of our country and the specialty of transplantation as practiced in the United States.

The ultimate answer to the issue of whether foreign patients should receive cadaver kidney transplants performed in the United States utilizing kidneys from deceased U.S. citizens will be to assist in improving the quality of medical care and the development of effective cadaver organ donor programs in other countries. Transplant surgeons in the United States have already contributed substantially to such efforts, both in hosting foreign surgeons and other transplant specialists, and in lecturing and teaching abroad. We are most willing to provide further assistance in the future.

I wish to thank you again for the opportunity to present this testimony.

Table 1. Native countries of the 25 non-resident aliens who are known to have received related transplants in the U.S. during 1982

Mexico	3
Saudi Arabia	2
Venezuela	2
Bolivia	1
Colombia	1
Costa Rica	1
Ecuador	1
Egypt	1
Greece	1
Guatemala	1
Lebanon	1
Taiwan	1
Turkey	1
Not specified	8

Table 2. Native countries of the 117 non-resident aliens who are known to have received cadaver transplants in the U.S. during 1982

Saudi Arabia	39
Greece	16
Argentina	6
Italy	5
Venenzuela	5
Syria	4
India	3
Mexico	3
Japan	2
Iraq	2
Nigeria	2
Panama	2
Sudan	2
Turkey	2
Yemen	2
Brazil	1
Germany	1
Guatemala	1
Hungary	1
Iran	1
Israel	1
Kuwait	1
Pakistan	1
Philippines	1
Qatar	1
Russia	1
Spain	1
Tanzania	1
Viet Nam	1
Yugoslavia	1
Not specified	7

Table 3. Data relating to non-resident aliens who are either known to have received transplants or were on the transplant waiting list during 1982 at the 6 largest U.S. transplant centers

Center	total no. of transplants	non-resident alien related transplants*	non-resident alien cadaver transplants*	average size of waiting list	non-resident aliens on waiting list**
A	165	1 (0.6%)	4 (2.4%)	400	15 (3.8%)
B	159	2 (1.3%)	2 (1.3%)	200	2 (1.0%)
C	140	2 (1.4%)	13 (9.3%)	115	5 (4.3%)
D	132	1 (0.8%)	1 (0.8%)	100	1 (1.0%)
E	130	0 (0.0%)	0 (0.0%)	120	2 (1.7%)
F	121	0 (0.0%)	6 (5.0%)	200	20 (10.0%)

* data expressed as % relates to % of the total number of transplants performed

** data expressed as % relates to % of patients on the waiting list

Table 4. Data relating to non-resident aliens who are either known to have received transplants or were on the transplant waiting list during 1982 at the 8 U.S. transplant centers with 5 or more non-resident alien transplants

Center	total no. of transplants	non-resident alien related transplants*	non-resident alien cadaver transplants*	average size of waiting List	non-resident aliens on waiting list**
C	140	2 (1.4%)	13 (9.3%)	115	5 (4.3%)
G	44	1 (2.3%)	12 (27.2%)	35	4 (11.4%)
H	18	1 (5.6%)	7 (38.8%)	15	7 (46.7%)
F	121	0 (0.0%)	6 (5.0%)	200	20 (10.0%)
I	44	0 (0.0%)	6 (13.6%)	68	1 (1.5%)
A	165	1 (0.6%)	4 (2.4%)	400	15 (3.8%)
J	57	0 (0.0%)	5 (8.8%)	30	2 (6.7%)
K	15	0 (0.0%)	5 (33.3%)	50	18 (36.0%)

* data expressed as % relates to % of the total number of transplants performed

** data expressed as % relates to % of patients on the waiting list

Mr. Gore. Well, thank you again for the chance we've had to work together.

Let me, before going to our next witness, let me say by way of explanation that the chart we put up there is not from your study. It is from the study done by the Health Care Financing Administration at the request of the subcommittee. I did want to note for the record that the center doing the largest number of nonimmigrant alien transplants is the Downstate Hospital in New York. I believe that was one of the ones which did not respond to your society's study.

Dr. Feduska. That is correct, Mr. Chairman.

Mr. Gore. To that extent—and we don't know how large that would affect it—but to that extent, that would affect the percentages and the numbers given.

Dr. Feduska. That's correct.

Mr. Gore. We will get into that.

You had some hospitals reporting to you that HCFA didn't get and HCFA had some that wouldn't respond to you, and we're putting them together. It doesn't markedly change the numbers, but it gives a range of 3 to 7 percent nationally, and it indicates that some centers are way above that, 50 percent, and in prior years as high as 70 percent of all patients being nonimmigrant aliens. But nationally it is 3 to 7 percent. We'll come back to that in some questions.

It is a real honor and privilege to introduce our next witness on this panel, Amy Peele, president of the North American Transplant Coordinator Organization. This organization, too, is one which we have been privileged to work with and we appreciate the good working relationship and cooperation that we have enjoyed in this mutual effort.

Miss Peele, we're looking forward to your testimony.

Ms. Peele. Thank you.

Representative Gore, members of the committee, my name is Amy Peele, senior transplant coordinator at Rush-Presbyterian-St. Luke's Medical Center, Chicago, Ill., and president of the North American Transplant Coordinators Organization, NATCO. I welcome the invitation to testify before this committee on behalf of Rush and NATCO.

The North American Transplant Coordinators Organization, NATCO, is a national, nonprofit organization representing over 400 professionals in the United States, Canada, and several foreign countries. The members of NATCO represent various areas of the transplant community and include physicians, nurses, and allied health professionals.

The role of the transplant coordinator varies greatly across the country according to the needs of the institutions for which they work. Some coordinators work only with the recipients, while others are solely responsible for the procurement and distribution of organs. NATCO provides a forum for information exchange within the transplant community and is active in professional and public education. However, NATCO, as an organization, does not dictate to its members protocol for the placement of cadaver kidneys. These activities are conducted by individual transplant centers or organizations.

For the purposes of this testimony, I will discuss the general criteria that procurement coordinators use in the placement of kidneys. I will specifically elaborate on the placement of cadaver kidneys at my own institution.

Generally, coordinators responsible for the placement of kidneys follow local guidelines and then attempt to place them regionally, nationally, and then as a last resort, overseas. When considering the time and work necessary to obtain these kidneys, returning to the donor families with a positive report of placement is the goal of each coordinator.

Every donor is truly different. Criteria influencing the placement of kidneys includes: The donor age and condition at the time of retrieval; blood type and tissue type; anatomy of the kidney; mode of preservation used, cold storage or machine; length of time kidney has been perfused after removal; sensitization of the patient; the immediacy need of the patient; and the philosophy of transplant surgeon accepting the kidney.

All of these criteria, either singularly or in combination, will ultimately determine where the kidney gets placed.

The organ procurement and preservation program at Rush-Presbyterian-St. Luke's provides technical support to renal transplant surgeons practicing at Rush. Decisions regarding the admission of a potential recipient to our transplant program, the urgency with which a transplant is required, and the suitability of a kidney for transplantation are made solely by our transplant surgeons. As these patients are seen at Rush as part of the physicians' private practices, the program has not established a position with respect to these physicians' activities.

In general, the organ procurement and preservation program does not knowingly differentiate between medicare and nonmedicare patients with respect to their priority for receipt of human organs or tissues for transplantation. Cadaver kidneys procured by this program are offered to the transplant community on the basis of histocompatibility match and clinical history of the donor. Tissue typing in the State of Illinois is centralized at the University of Illinois Medical Center and kidneys are placed in a common donor pool for distribution to any of the Illinois transplant centers having a suitably matched recipient. A copy of the priority system utilized by the University of Illinois tissue typing lab is included to further clarify placement of kidneys in Illinois. To the best of my knowledge, no consideration is given to the ethnic and/or racial background of either the donor or recipient, other than where these characteristics have clinical significance. Kidneys are offered to programs outside of Illinois only after confirming that no Illinois program has an interest in transplanting this kidney.

Recipient identification outside of Illinois is handled through our participation in the United Network for Organ Sharing. This national donor/recipient matching program matches patients by tissue type, blood type, and degree of sensitivity. There is no mechanism to identify nonresident alien recipients. A kidney is offered to a given program and, upon acceptance, that program is responsible for reimbursing this medical center's standard acquisition charge.

In the event a suitable recipient cannot be identified, we will continue to call potential recipient centers in the event they have recipients pending outside of the donor/recipient matching program. Only upon exhaustion of all U.S. recipients have we considered contacting foreign programs. To date, we have provided kidneys to programs in Italy, Kuwait, Europe—through Euro-Transplant—Turkey and Spain. The rationale for contacting these programs is strictly humanitarian.

During the calendar years of 1981 and 1982, 18 transplants were performed at Rush each year. To date, 38 transplants have been performed during 1983. During this 3-year period, five transplants were performed on nonresident aliens. As these patients are referred to an individual transplant surgeon and become a part of the surgeon's private practice, they are treated by our program as any other endstage renal disease patient. The program has no agreements with foreign governments, either regarding the transplantation of their patients or the provision of cadaveric kidneys to their programs.

We have attempted to deal with the issue of foreign nationals receiving kidney transplants at Rush and having a portion of their procurement-related charge subsidized by the endstage renal disease program. At the time a patient is presented to the program as a potential transplant recipient, we determine the patient's medicare status. In the event of a nonresident alien, a notation is made to segregate this patient's bills from the general recipient pool.

We do not treat these patients any differently than our medicare recipients for purposes of organ acquisition. When kidneys are accepted for these patients from outside programs, the program is often required to reimburse the procurement center a standard acquisition charge greater than our usual charge to the patient. Rather than subsidize this difference with end-stage renal disease funds, we charge a nonresident alien patient the actual expense incurred with a nominal adjustment for the staff time required to provide this kidney for surgery. These bills are guaranteed by the surgeon's private practice. To the best of my knowledge, I am not aware of any foreign nationals who have been placed out of turn at the head of any transplant priority list at our medical center.

In closing, the issues surrounding the distribution of this valuable resource are complex and highly emotional. As a procurement center, we attempt to place organs with the recipients having the greatest likelihood of a successful transplant. We subscribe to the policy that the decision regarding organ or tissue utilization should be based on clinical grounds exclusively and remain the responsibility of the recipient's physician. When an organ or tissue is discarded for lack of a suitable recipient, it becomes a loss to mankind in general.

It is important that the allocation of kidneys to foreign nationals be discussed openly, as it is here today. Please understand, under the current system of procurement the procurement coordinators are the ones who actually gather and relate the data utilized when transplant surgeons make their decisions on accepting or rejecting kidneys.

On behalf of the NATCO membership, I thank you for the opportunity to discuss this issue, and we look forward to assisting in the definition of a national system that will clearly assure fair and equal distribution of organs.

Mr. GORE. Thank you very much, and thank you for all that you do on a daily basis.

Our next witness is Dr. John McDonald, president of the South-Eastern Organ Procurement Foundation. Dr. McDonald, to you as well, I would like to express my thanks for the chance to work with you, and I would like to also acknowledge the fine work of your executive director, Gene Peirce, who is here today and has been extremely helpful, also.

Dr. McDonald, please proceed.

Dr. MCDONALD. Thank you, Mr. Chairman.

I am professor and chairman of the department of surgery and surgeon in chief at the Louisiana State University Medical Center in Shreveport, La. I am here to testify primarily in my capacity as the president of the South-Eastern Organ Procurement Foundation, but I will also make some remarks as the director of a University Transplantation Service.

The South-Eastern Organ Procurement Foundation is a nonprofit organization dedicated to the improvement of transplantation by fostering organ donation, organ sharing, and quality control of the pertinent sciences. It is comprised of 44 separate transplantation centers that occupy the geographic areas roughly bounded on the four corners by New Jersey, Indiana, Louisiana, and Florida. These 44 transplant centers relate to one another through the South-Eastern Organ Procurement Foundation according to an established set of bylaws.

The foundation has pioneered in computerized matching techniques and computerized quality control of organ procurement, tissue typing, and data collection. It should be understood that each of the 44 centers either is, or is associated with, a local organ procurement group. When an individual group retrieves organs for transplantation, the retrieving group has the option to use or not to use those organs for their own patients based upon their own local guidelines.

However, should organs become available that the individual center does not choose to use locally, then that center would access the computer at the headquarters of the South-Eastern Organ Procurement Foundation for the purpose of locating an appropriate recipient according to established criteria. These include the sensitization of the patient, the degree of compatibility between the organ and the recipient, and the clinical status of the potential recipient. A copy of the standard prioritization practices of the Foundation is included in the standard manual that is here for your formal record.

There are now some 3,000 patients registered in the SEOPF computer awaiting kidneys, and a much smaller number awaiting other organs. During the past 3 years, approximately 1,000 kidneys per year have been shared among the centers of SEOPF each year. Patients registered on the SEOPF computer are registered by name and by the institution responsible for their care, and we do not have information as to their national origin.

The South-Eastern Organ Procurement Foundation does not have a policy regarding the transplantation of tissues to foreign nationals when the transplant takes place within the United States. That issue has not been raised within the councils of the foundation, presumably because it has been considered principally a local issue.

There are two ways that an individual transplant center may elect to share its kidneys with other centers. One is to obtain the appropriate printout through the computer of available recipients and make its own contacts with other centers that might wish to obtain the organs. The other way is through a centralized "Kidney Center" in which the harvesting institution may report the data to the center and the center is responsible for placing the organ elsewhere.

The foundation does have written policies regarding placement of organs by the central kidney center. Every effort is made to place the organs in the United States. If that is not possible, the organ will be placed in a foreign country, if possible. We attempt first to place the organ in a country that pays the entire acquisition cost, and if this is not possible, rather than discard the organ, it will be placed in a country which pays only transportation costs.

Within the past year we have transferred 170 kidneys outside of the United States, and they have gone to the countries as listed in the table in my written report.

In addition, the South-Eastern Organ Procurement Foundation has made its own computer and its computerized programs available to the remainder of the United States through a system called the United Network for Organ Sharing. This now includes some 90 percent of the Continental United States with a total of 140 transplant centers who elect to register their patients through the UNOS system and make them available for organ sharing. The same principles apply to all the participants in the UNOS system as to the SEOPF system, except that they are not involved in data acquisition or quality control or serum sharing programs of SEOPF. There are some 3,000 patients registered through the UNOS system on our computer and, therefore, the available patient pool is roughly 6,000 covered by this system.

I shall now make some comments about my own transplant center at the Louisiana State University in Shreveport. We have had a policy of not accepting nonresident aliens into our patient population, primarily because we did not feel that it was an appropriate allocation of scarce resources. We were personally fearful that if we had nonresident aliens waiting on our own list that we would use organs locally that we would otherwise have shared with other institutions and thereby in a secondary way deny kidneys to American citizens.

I am aware that there are some centers in the country who do accept foreign nationals for kidney transplantation. Some of those centers accept patients who have a related donor and it seems to me that with the success rate today, that that poses a very minimal problem.

I do not personally know, nor is the information available to SEOPF, how widespread it is the practice of obtaining kidneys from American citizens and placing them into foreign nationals. The data, first heard by me this morning, accumulated by the American Society of Transplant Surgeons, and just presented by

Dr. Feduska, confirm my prejudice or opinion that this is such a small problem in terms of percentages that no uniform policy is probably required to approach this issue today. Most physicians and surgeons take the view that medicine should be considered—should not be considered in nationalistic terms, that it is a humanistic discipline, and that their services and skills should be made available to all citizens of the world. As long as this is not a problem of substantial magnitude, it might best be left alone.

Some countries, such as England, for example, have passed legislation requiring that English kidneys be placed in English citizens. There are other countries in the world, particularly a number of Arabic nations, in which cadaver organ donation is forbidden or prohibited by religion or law, and therefore no post mortem organ donation is feasible from these countries. Thus, a major part of the problem of international organ sharing that was discussed earlier this morning is that some countries do not obtain their fair share of organs, and thus are consistent takers rather than sharers.

That concludes my remarks, Mr. Chairman.

[The prepared statement of Dr. McDonald follows:]

John C. McDonald, M.D.
Testimony - House of Representatives
November 7, 1983

I am here to testify primarily in my capacity as the President of the South-Eastern Organ Procurement Foundation. I will also make some remarks as the Director of a University Transplant Service.

The South-Eastern Organ Procurement Foundation is a non-profit organization dedicated to the improvement of transplantation by fostering organ donation, organ sharing, and quality control of the pertinent sciences. It is comprised of 44 separate transplantation centers that occupy the geographic areas roughly bounded on the four corners by New Jersey, Indiana, Louisiana, and Florida. These 44 transplant centers relate to one another through the South-Eastern Organ Procurement Foundation according to an established set of bylaws. The Foundation has pioneered in computerized matching techniques and computerized quality control of organ procurement, tissue typing, and data collection. It should be understood that each of the 44 centers either is, or is associated with, a local organ procurement group. When an individual group retrieves organs for transplantation, the retrieving group has the option to use or not to use those organs for their own patients based upon their own local guidelines. However, should organs become available that the individual center does not choose to use locally, then that center accesses the computer at the headquarters at the South-Eastern Organ Procurement Foundation for the purpose of locating an appropriate recipient according to established criteria. These include the sensitization of the patient, the degree of compatibility between the organ and the recipient, and the clinical status of the potential recipient. A copy of the standard prioritization practices of the Foundation is included in my written report. There are some 3,000 plus patients registered on the SEOPF computer awaiting kidneys and a much smaller number awaiting other organs. During the past three years approximately 1,000 kidneys per year have been shared among the centers of SEOPF each year. Patients registered on the SEOPF computer are registered by name and by the institution responsible for their care and we do not have information as to their national origin.

The South-Eastern Organ Procurement Foundation does not have a policy regarding the transplantation of tissues to foreign nationals when the transplant takes place within the United States. That issue has not been raised within the councils of the Foundation, presumably because it is principally a local issue. There are two ways that an individual transplant center may elect to share its kidneys with other centers. One is to obtain the appropriate printout through the computer of available recipients and make its own contacts with the other centers that might wish to obtain the organs. The other way is through a centralized "Kidney Center" in which the harvesting institution may report the data to the center and the center is responsible for placing the organ elsewhere.

The Foundation does have written policies regarding placement of organs by the central Kidney Center. Every effort is made to place the organ(s) in the United States. If that is not possible, the organ will be placed in a foreign country if possible. We attempt first to place the organ in a country that pays the entire acquisition cost. If this is not possible, rather than discard the organ, it will be placed in a country which pays only transportation costs.

Within the past year we have transferred 107 kidneys outside of the United States and they have gone to the following countries:

Kuwait	19
Rome	4
Turkey	51
England	7
Costa Rica	1
Brazil	1
Japan	3
Argentina	7
Euro Transplant	11
Spain	2
Singapore	1

In addition, the South-Eastern Organ Procurement Foundation has made its own computer and its computerized programs available to the remainder of the United States through a system called the United Network for Organ Sharing. This now includes some 90 percent of the continental United States and a total of 144 transplant centers who elect to register their patients through the UNOS system and make them available for organ sharing. The same principles apply to all of the participants in the UNOS system as to the SEOPF system except that they are not involved in data acquisition or the quality control or serum sharing programs of SEOPF. There are some 3,000 patients registered through the UNOS system on our computer and, therefore, the available patient pool is roughly 6,000 in the United States covered by these systems.

I shall now make some comments about my own transplant center at the Louisiana State University Medical Center in Shreveport. We have had a policy of not accepting non-resident aliens into our patient population primarily because we did not feel that it was an appropriate allocation of scarce resources. We were personally fearful that if we had non-resident aliens waiting on our list that we would use organs that we would otherwise have shared with other institutions and thereby in a secondary way deny kidneys to American citizens. I am aware that there are some centers in the country who do accept foreign nationals for kidney transplantation. Some of those centers accept patients who have a related donor and this certainly poses no problem. I do not personally have, nor is the information available to SEOPF, of how widespread is the practice of obtaining kidneys from American citizens and placing them into foreign nationals. Such data are being accumulated by the American Society of Transplant Surgeons. It is my personal opinion that when the data are compiled, they will indicate that this is a small group of patients and probably no uniform policy is required to approach this issue. Many physicians and surgeons take the view that medicine should not be viewed in nationalistic terms, that it is a humanistic discipline, and that their services and skills should be made available to all citizens of the world. As long as this is not a problem of substantial magnitude, it might be best left alone.

Some countries, such as England for example, have passed legislation requiring that English kidneys be placed in English citizens. There are other countries in the world, particularly a number of the Arabic nations, in which cadaver organ donation is forbidden or prohibited either by religion or law, and therefore, no postmortem organ donation is feasible from those countries.

A part of the problem of internatinal organ sharing is that some countries do not obtain their fair share of organs and thus are consistent takers rather than sharers.

Mr. GORE. Thank you very much. I have a number of questions as a result of that. We will come back to them.

Dr. Paul Terasaki is Director of the Southern California Regional Organ Procurement Agency and is president of the International Society of Transplant Physicians—is that correct?

Dr. TERASAKI. Yes; that's correct.

Mr. GORE. We are honored to have you here and please proceed.

Dr. TERASAKI. Chairman Gore, every week there are about a hundred patients who are transplanted with a kidney. There are about 108 kidneys that are salvaged every week, and about 8 of them are discarded. In addition, about one a week is sent out of the country. What I would like to do is address myself to the question of why it is that we have a shortage of kidneys in the United States and why it is we are shipping 1 percent of the kidneys out of the United States.

First of all, with regard to the 8-percent discard rate, most of the reason is anatomic. Oftentimes when a patient is operated on we find that one kidney is OK but the other kidney has multiple arteries, there are other various anatomic defects to the kidney. In addition, there are some patients who have other problems. For example, there may be patients with pneumonia, patients with herpes, so that they are marginal donors. In fact, recently we shipped out a kidney from a patient who had syphilis. It is questionable whether such a donor is a good donor or possibly useful as a donor.

So about one-third of the kidneys that are shipped out are bad kidneys. The other two-thirds of the kidneys that are shipped out are shipped out because there is no recipient in the United States for that kidney.

Now, it may seem strange that there are 60,000 patients on dialysis, why on a given day there wouldn't be a recipient. First of all, with a type A kidney, we know that only 24,000 of the dialysis patients are blood group type A. The second very important problem is that all those 24,000 patients are not on a transplant list. Only about 10 percent of the patients who are on dialysis are on transplant lists, so that that then cuts the pool down to about 2,000 type A patients.

A third problem is that some of the patients are immunized. About three-quarters of the type A patients are immunized, so now we are down to about 700 patients from which we are trying to make our selection.

Mr. GORE. Excuse me. When you say sensitized and immunized, could you elaborate on that a little bit?

Dr. TERASAKI. Yes. Some patients have already rejected a transplant. They become immunized by rejecting a transplant and the possible donors that could be considered for that patient becomes a lot less. In fact, there are many patients who are immunized to 90 percent of the population; that means 90 percent of the donors would not be suitable for that patient.

Mr. GORE. Now, why would that be more common with type A patients than with the other blood types?

Dr. TERASAKI. It turns out that it is possible to transplant from O to A, but not from A to O. And because of that problem, through these years, the last 15 years, there have been kidneys transplanted from type O to type A patients. This has disturbed the balance of nature, so that today in the waiting pool there's a lot more type A's than there should be.

Mr. GORE. Now, wait a minute.

Dr. TERASAKI. I mean——

Mr. GORE. Run through that——

Dr. TERASAKI. I mean, there's a lot more type O patients than there should be, a lot less type A patients.

Mr. GORE. Now, you can transplant from type O to type A?

Dr. TERASAKI. A, yes.

Mr. GORE. You cannot transplant from type A to type O.

Dr. TERASAKI. Yes, that's correct.

Mr. GORE. Now, why has that disturbed the balance? Explain that to me.

Dr. TERASAKI. In nature there is 40 percent type A and 40 percent type O, approximately. Now, if we—that's in the patients. Now, in the donors, it's the same, about 40 percent are type A and 40 percent are type O.

Now, if you transplant from the O's to the A's in the recipients, you're going to start getting rid of the A patients, or transplanting the A patients, winding up with many more type O patients. So eventually we wind up with a state where we have type A donors coming out and not enough type A recipients waiting for the kidney.

In addition——

Mr. GORE. But out of 60,000 patients on dialysis, 24,000 are type A?

Dr. TERASAKI. A, yes. As I mentioned, only 10 percent of those patients are on a transplant list. This is the fact that you mentioned earlier, that 90 percent of the patients that are dialyzed are not even considered for transplant.

Mr. GORE. Why?

Dr. TERASAKI. Well, we think it is one of the major problems that should be investigated, that many patients are stuck on dialysis, are not being considered for transplants.

Mr. GORE. Why aren't they being considered and why aren't they being put on the transplant list?

Dr. TERASAKI. I don't know, but I think it has to do with patients being under the care of certain doctors, and then having to be transferred to the care of other doctors. The dialysis physicians are taking care of their patients on dialysis. There may be some problems about referring those patients to the transplant physicians.

Mr. GORE. So a turf battle between nephrologists and surgeons could prevent 90 percent of those on dialysis from being referred to transplant lists?

Dr. TERASAKI. Well, I'm not sure of the exact reasons, but I'm sure you are aware of the facts. You mentioned 60,000 patients are on dialysis. There are 6,000 patients waiting for a kidney. That's only 10 percent of the dialysis population.

Mr. GORE. Yeah, but I was—I'm learning more and more about this whole subject as we are looking into it more deeply. But I was under the impression that there were some kind of medical reasons for the sharp limitation in the numbers that were put on the transplant list.

Dr. TERASAKI. Yes. We should state there are medical reasons. For example, there are many patients who are dialyzed who are old patients———

Mr. GORE. Age is one factor. All right.

Dr. TERASAKI. Yes, age is one of the major factors. There are other kinds of medical contraindications for transplants, but———

Mr. GORE. But there are organizational and economic problems that influence that outcome as well. Is that what you're telling me?

Dr. TERASAKI. Yes. The conservative estimates are that at least 30 percent of those being dialyzed should be eligible for transplants, should be good candidates for transplants.

Mr. GORE. Instead of 10 percent?

Dr. TERASAKI. Instead of 10 percent.

Mr. GORE. Well, that's the most significant thing I've heard today. I mean, we've got to get some changes.

Dr. TERASAKI. Yes.

Mr. GORE. We've got to produce some changes. In other words, there are 15,000 patients out there right now on dialysis who should be on a list for transplantation, but are not on a list for transplantation, and don't even know that they're candidates for transplantation. And you're telling me as a doctor that one of the reasons for it is that the doctors now taking care of them are reluctant, for whatever reason, to transfer control of that patient over to a specialty that is more oriented toward transplantation; is that what you're telling me?

Dr. TERASAKI. Yes.

Now, to be fair, I have actually worked in transplantation for 25 years, so this is somewhat of a bias. But———

Mr. GORE. And we don't have any nephrologists, do we? We do, on the next panel. Excuse me.

Dr. TERASAKI. But I think it's correct that the field of transplantation has been getting better and better recently, and previously it was a case that if you were being dialyzed, you might want to think twice about being transplanted, that the risk of transplantation was perhaps too much for you. But the situation has changed a lot, so that nowadays there is only a 10-percent chance of dying on transplants in the first year. Ninety percent of the patients who are transplanted survive the first year with the cadaver donor. That is the statistics from throughout the country.

Mr. GORE. OK. Please proceed. I'm sorry to interrupt.

Dr. TERASAKI. OK. So what I was trying to do was to go through the reasons why today there is a chance that we wouldn't find a single type A recipient suitable for a kidney that we get. First was the problem that some of the—that many of the patients are not on the list; second, that those who are on the list, many of them are immunized—three-quarters are immunized, incidentally, because these type A patients tend to pile up because of the problem that I mentioned, of type O's being transplanted to A's.

Then the second problem is the tissue matching. I have been principally working in this area of tissue typing and we see that the chance of getting a perfect match is 1 in 100,000 so it's very difficult to get a good tissue typing match with donors and recipients. If we try to get a good match, we find that oftentimes it is not possible. So because of this, then, 143 kidneys in the last 2½ years have been shipped to Japan.

Now, you might ask why is it they have been shipped to Japan and not to, let's say, Canada, or to Europe. Dr. McDonald has just mentioned the main reason. The main reason is that everyone wants to ship to a country where they will be reimbursed for their expenses. In Japan, the patients themselves have agreed to pay for the kidney. So they pay $5,000 for each kidney—or $6,000.

The Government of Japan does not pay for the kidney, and we have been trying to get the governments of other countries to pay for the kidneys—for example, England, Canada, Mexico—so that it should be possible in the future to send kidneys to any country in the world.

Now, we also see that if you look in Europe, the same kind of situation exists. From France, kidneys are not shipped to England; from Germany, they are not—from Germany they are not shipped to Denmark, they're not shipped to France. In all the different countries in Europe we have a situation where each country feels that the kidneys obtained in their country must stay within their own boundaries.

If we look at the history of transplantation, we have a situation where initially in the early days of transplants, a surgeon found a kidney, he would say that this kidney that I have salvaged should go into my own patient. Subsequently, we have had a situation where, for example, at UCLA, a kidney that is harvested at UCLA should go to a UCLA patient and not to a USC patient.

We have moved from that type of thinking to looking at Los Angeles as a whole and saying that kidneys salvaged in Los Angeles should be for Los Angeles citizens. There has been—most of the kidneys salvaged in Los Angeles, actually 75 percent are actually transplanted within the Los Angeles area.

In my presidential address last year in Brighton, I have dealt with this problem, that is, the question of trying to share kidneys widely, not just in one area, not just in one country, but throughout the international community. We think that the very fact that transplantation exists today is because of collaboration in the scientific community throughout the world. In fact, my own training was in England and without that training I don't think I would be here today.

So I would look forward to the day when there is a free exchange of human tissues throughout the world. And I do understand the feeling of patients, that they should get kidneys preferentially, but eventually they should be able to get better matched kidneys from throughout the world.

I think that your bill, H.R. 4080, is very important in allowing us to generate more kidneys, because this is the most important thing that we must do immediately. The second most important thing is that we must work on the lack of recipients, that is, that only 10 percent of the patients being dialyzed are on the recipient list. And lastly, I would like to just mention that with regard to the selling of organs, in my capacity as president of the International Transplant Society, the Transplant Society has decided that they would expel any member in the society who is involved in the buying of kidneys from living donors. The other—the American Society of

Transplant Surgeons, and the American Society of Transplant Physicians, have joined with us in agreeing that we will expel any members doing this act.

Thank you very much.

[The prepared statement of Dr. Terasaki follows:]

TESTIMONY FOR THE COMMITTEE ON SCIENCE AND TECHNOLOGY
UNITED STATES HOUSE OF REPRESENTATIVES

At the Request of Albert Gore, Jr., Chairman
Subcommittee on Investigations and Oversight

By Paul I. Terasaki, Professor of Surgery
UCLA School of Medicine, Los Angeles, California

I am the Director of the UCLA Tissue Typing Laboratory and Director of the Southern California Regional Organ Procurement Agency (ROPA). We have been functioning as the central distribution point for kidneys obtained in Southern California since 1968. Our chief function has been to encourage and achieve a better exchange of kidneys among the 12 kidney transplant hospitals in the Southern California area. Although UCLA has a transplantation program, my prime role is with ROPA rather than in the medical school's transplant program. The answers that I provide for your questions are, accordingly, in that capacity.

1. The transplant centers in the Southern California area have all agreed to use HLA-DR matching as the primary means of allocation for transplants. Priority is also given to patients who are highly sensitized. Transplant centers that remove the kidneys have priority over others if other factors are equal.
2. We have no policy regarding nonresident aliens. Since the fraction of such patients has been small (under 5%), we have not considered this potential problem.
3. The number of cadaver donor transplants done through the Southern California ROPA was 230 in 1981, 270 in 1982, and 263 in 1983 (as of September 30). It is very difficult for us to determine who is a foreign national since we have not kept records on this point. In 1982, however, there were 16 apparent Arabic names out of 270 transplants. It is possible that some of these patients are United States citizens, but if we assume that they were all Arabic, the percent is 5.9%. There are probably only a few patients from other countries.

4. The aliens are entered on the list by the transplant centers and we at ROPA have no direct arrangements with the patients.
5. ROPA or I have no agreements with foreign governments.
6. There is no difference in charges for kidney acquisition to any patient.
7. No foreign nationals are placed on the list out of turn by the coordinators of our organization.
8. I do not believe that a uniform national policy is required for nonresident aliens at the present time. However, it is important to record the extent of such transplants and eventually require a ceiling if a problem develops. Perhaps one method would be to require that, within each region, the number should not exceed a certain percentage.
9. The most important ethical consideration for the allocation of kidneys is that no kidney be wasted. Today, there is considerable wastage from various sources. The worst problem is failure to obtain kidneys from suitable patients who have died. HR4080 provides for federal grants to deal specifically with this problem, The second source of waste is that, even after the removal of kidneys, the kidneys are being discarded for lack of a suitable recipient. It may seem strange that with 60,000 patients on dialysis, there are days when not a single recipient can be found for a given kidney. The most frequent reason is that the kidney is blood type A and there are no suitable recipients with blood type A in the entire country. Of the 60,000 patients on dialysis, 24,000 of them are blood type A. It frequently happens that not a single one of them is available for transplantation and the kidney is discarded. Why is this?
    A. Many patients being dialyzed are not suitable candidates for transplantation, though at least 30% of those being dialyzed should be available, in which case, on any given day, there should be 7,200 blood type A patients on dialysis waiting for a transplant. The problem is, only about 10% (700) of these patients are on a transplant list throughout the country.

This is the primary reason for the waste. In other words, patients who are suitable for transplantation are not actually being considered for transplantation by their dialysis physicians. The ESRD regulations are not stringent enough to make qualified dialysis patients aware of transplantation. Some dialysis centers never refer their patients for transplantation.

B. Of the 700 or so type A patients listed, approximately 75% are already immunized and are therefore difficult to match. The percentage of type A patients who are immunized is high since these patients have accumulated over the past 15 years in the pool. In the past, transplant centers have tended to transplant their own patients and not share kidneys on the basis of ABO matching, resulting in an imbalance in the natural random distribution of blood types.

C. As the evidence for efficacy of histocompatibility improves, more centers are reluctant to transplant patients with the worst possible matches. If we try to obtain fairly good HLA matches, the pool of 700 A patients, reduced to 175 by immunization, is entirely insufficient in numbers. Thus, despite extensive national kidney sharing, there are many nights when a home cannot be found for a blood type A kidney in the entire United States.

10. As far as I know, most countries handle the question of allocation of organs similarly to us. This applies to the United Kingdom, Australia, Scandinavia, Germany, France, Switzerland, and Japan. Although I do not know whether there are set policies, I do know that in these areas of active transplantation, citizens from other countries are given kidney transplants. For example, patients from Greece and Italy are transplanted in Northern European countries and some Saudi Arabians are transplanted in England. I would imagine that their attitude is the same as in the United States, that is, that their own citizens should be served first but, if possible, help for citizens of less privileged countries is tolerated.

11. Kidneys are sent out of the United States only when there are no recipients in the United States who are suitable for the kidneys. Speaking for the kidneys that we arrange to ship, the scientific basis is given in the enclosed publication. Briefly stated, the rationale is as follows.

My principal line of work has been in the development of histocompatibility typing and attempting to use histocompatibility for the selection of the best-matched donor and recipient. I have been personally involved in this endeavor for more than 25 years. We have attempted to match donors and recipients despite the immense problem created by the fact that there are many different tissue types that exist in the human race and it is extremely difficult to obtain a perfect match within the entire country and possibly the entire world. Since there are more than 80 different tissue types combined in different ways, one can say that the chance of obtaining a perfect match is somewhere around 1 in 100,000. This means that in order to do matched transplants, a pool of 100,000 patients is needed. Those of us who are involved in histocompatibility therefore think that we must eventually move toward an international pool of waiting recipients. The concept of developing such an international pool was the subject of my Presidential Address given last year when I was inaugurated as President of the International Transplant Society. It is with this objective in mind that we have taken the first real steps towards international sharing. In the early days, when a surgeon removed a kidney, he assumed that this kidney would be for his own recipient. Through the years, most regional areas have come to share kidneys between hospitals within their region. However, we should note that, even today, there are many large regions in the United States where at least 90% of the kidneys salvaged in that region remain within that region and are not shipped out. They are only shipped out as a last resort when the kidneys cannot be used in that region.

It is amusing to see that in Europe there is Euro Transplant, Scandia Transplant, France Transplant, Swiss Transplant, United Kingdom Transplant, and Italia Transplant. All of these different organ procurement organizations keep most of their kidneys within their organization and kidneys are shipped out when they cannot be used. "Euro Transplant" is actually Holland, Germany, Belgium, and does not include the major transplant areas such as England, Scandinavia, France, or Switzerland. In a similar way, kidneys are rarely shipped across the river from Detroit to Toronto or from Seattle to Vancouver.

My proposal has been to try to break down these barriers and to make international sharing of kidneys possible as explained in the attached reprint. The need might be greater in Europe than in the United States, but I believe that the concept is one which we should try to promote. In order to do this, we started shipping to Japan approximately two years ago.

In 1982, 68 kidneys were shipped, which was 1.3% of the 5,000 kidneys transplanted in the United States. It should also be noted that we only arranged for the shipment and that the actual shipping center has been diverse (Texas, Nebraska, Florida, Hawaii, Kansas, Colorado, Ohio, New York, Oregon, Kentucky, Indiana, Nevada, New Jersey, Utah, Pennsylvania, Washington, D.C., Arizona, etc). The charge for the kidneys has been a uniform $6,500 which was paid to the shipping center. We acted as the coordinating center and assessed $500 per kidney. The expenses involved were: coordinator on call, base pay, shipping charges, cross-matching, and international telephone expenses. Of the total of 143 kidneys sent, most were types A, B, or AB. Of the total of 143 kidneys sent, only 10 were type O and most were pediatric, had multiple vessels and infections such as herpes, meningitis, and pneumonia. Sich kidneys are generally not accepted for adult transplants in the United States.

We have spoken to transplant physicians in Canada, Mexico, and England about future kidney shipments. I believe that in the future, exchange of organs should be agreed upon by the different governments. Without some way of equitably covering the cost, international sharing of organs is not possible. For example, if the kidney is sent to Europe today, reimbursement is not possible for any of the expenses except those involved in the shipping. This is the principal reason why kidneys do not cross the Atlantic. In Japan, the patients have agreed to pay $7,000 of their own funds if they should receive a kidney. We have tried all possible ways to persuade the Japanese government to pay for the kidneys so that kidneys could go to everyone without regard for their ability to pay. However, the Japanese Ministry of Health, which is already overcommitted on kidney dialysis, is reluctant to pay for kidney charges. We should also note that kidneys to Japan have been sent partly for the purpose of stimulating their own cadaver donor programs. Because of religious reservations, it has been difficult to obtain kidneys from cadaver donors. However, following shipment of U.S. kidneys, cadaver donor donations from the Japanese population have increased by 100%.

We have gained several important pieces of scientific information from this experience. First, we know that it is possible to store kidneys in a simple solution for as long as 60 hours. Second, HLA-DR matching is shown to be important to the outcome of transplantation. Poorly matched HLA-DR transplants have not survived as well as the optimal matches. These studies have also shown that transplants of organs matched for HLA types completely neutralize the fact that the donor and recipient are of different racial groups (as in blood transfusions).

In Summary, I believe that, currently, the abuse of ESRD funds and resources is negligible. The foreign nationals pay for all their hospital expenses and for the kidneys that are shipped to them by the transplant centers.

With respect to allocation of this invaluable, scarce human resource, it is important to consider the broader issues of achieving the maximal usage of every cadaver donor kidney. It is not yet clear to what extent transplantation into patients who are matched for HLA will prolong the function of kidneys. If, for example, an overall gain of 3 years per kidney can be achieved, obviously a national program of kidney sharing on the basis of typing would result in a high dialysis cost savings. I believe it is necessary to investigate the role of HLA-DR matching by shipping kidneys to matched recipients. To prepare for the future, extending the pools of waiting patients to an international pool will be important. Sharing up to 5% of kidneys internationally should yield data on the efficacy of tissue typing. Moreover, if kidneys are to be wasted at local levels, shipping mechanisms should be arranged.

Currently, even more pressing than the problem of non-Americans receiving kidneys is the problem of many Americans being dialyzed who are not being considered for transplantation. If 60,000 are being dialyzed, those who are suitable for transplantation are surely more than the 5,000 who are currently on the waiting lists for transplantation.

Mr. GORE. Thank you very much. We appreciate your support for the legislation, also.

Our final witness on this panel is Dr. Henry Krakauer, from the National Institutes of Health, from the Institute of Allergy and Infectious Diseases in Bethesda. Dr. Krakauer, we appreciate your presence here today, and please proceed.

Dr. KRAKAUER. Thank you, Mr. Chairman. Thank you for the opportunity to present information to you.

I appear before you as an expert, and I am prepared to discuss scientific matters. I cannot, of course, speak for my Institute, nor for the Department, on matters of policy. The information that I will present is based on the overview of the field of transplantation that I obtained as Chief of the Genetics and Transplantation Biology Branch of the National Institute of Allergy and Infectious Diseases, a position that I held until early this year. In that role, I was responsible for the administration of grant and contract supported research on the immunologic factors that determine whether a graft succeeds or fails. I was also assigned the responsibility for the development, acquisition, and distribution of materials needed for the identification of transplantation antigens to permit the matching of donors and recipients.

In addition, I performed analyses to identify which patient characteristics and which medical practices used in conjunction with transplantation are associated with higher or lower probabilities of success. In collaboration with the Health Care Financing Administration, and using the data of their medical information system, I analyzed the merits of dialysis and transplantation as treatments of end-stage renal disease and, using a mathematical model, projected the medical and fiscal impacts of changes in transplantation strategy.

Ideally, priority in the allocation of organ grafts—and I am assuming that it is, in fact, decided that setting of priorities is desirable—priority in the allocation of organ grafts should be based on an assessment of which potential recipient will benefit most. This requires knowledge of who is at highest risk of death or disability without the graft, and whose prospect of survival and return to useful activity following receipt of the transplant is the best.

Unfortunately, both aspects of the problem are highly complex, a consensus has not been achieved on either, and as far as I know, there is no generally agreed-upon system for the allocation of organ grafts at this time.

In the written statement which was previously submitted to you I outlined the priorities assigned to potential recipients of cadaveric kidneys by four organ-sharing organizations—the South Eastern Organ Procurement Foundation, and the New England Organ Bank in the United States, and the United Kingdom Transplant Service and Euro-transplant in Europe.

There is agreement in all four organizations on two absolute contraindications to the transplantation of a particular recipient with a given graft. Both are based on the presence in the blood of the recipient of antibodies which will react with structures called antigens on the cells of the donor and render rejection of the graft virtually certain. Medical urgency, usually defined as the imminence of death unless a transplant is performed, results in a patient being assigned a high priority for an organ, but is factored into the equation in different ways by different organizations. Broad sensitization—that is, the presence in the blood of the recipient of antibodies to transplantation antigens of a large proportion of the population—usually, but not always, results in the assignment of a higher priority.

Beyond this, the criteria become even less uniform. The most interesting variability is in the importance attached to the matching of transplantation antigens of the donor and recipient. This variability is based on medical uncertainty about utility, a common thread that runs through much of medical practice. Matching of the transplantation antigens of related donors and recipients—that is, in transplants involving siblings—such matching is extremely important. On the other hand, the evidence for the importance of matching of transplantation antigens is not decisive when the graft is from an unrelated cadaveric donor.

For example, in a large study conducted by the NIAID, a low level of mismatching of the HLA-A and B transplantation antigens—these are the ones that are most commonly identified now—such a low level of mismatching was associated with only a slightly higher probability of success than more extensive mismatching, and a high level of statistical significance was not achieved by this difference. Recently the 8th International Histocompatability Workshop obtained results that were equally unimpressive for HLA antigen matching.

By contrast, in another large study conducted by the South Eastern Organ Procurement Foundation, in which I participated in analyzing, HLA matching had a larger and much more statistically significant effect. And yet, as I understand it, the SEOPF dispenses with such matching in kidney transplantation when cyclosporin is used for immuno-suppression.

The Europeans are so fully convinced of the importance of matching that they have evolved rigid ranking based on the degree of matching and do not relax the criteria even when cyclosporin is used.

The disagreement on HLA matching between the NIAID and the SEOPF studies is but one of several involving factors that affect outcomes of transplantation. The root of the problem, the reason for the disagreement, is that there were large systematic differences between the two studies, both in terms of the populations enrolled and in terms of the medical practices used in conjunction with the transplantation. Nevertheless, despite the discordance on some of these factors, including HLA matching, there was agreement in the two studies on several other factors as predictors of a reduced probability of success in transplantation. These include, for example, diabetes as the initial cause of renal failure, rejection of a prior transplant, and a high level of sensitization. All of these were more important than HLA matching, even in the SEOPF study, and none of these, as far as I know, is used in any formal scheme for the setting of priorities in the allocation of organ grafts.

However, the measurement of the relative importance of such predictors of outcome is only now hitting its stride. For example, our study of the NIAID and SEOPF data only appeared last month.

I am confident that, as such studies gain acceptance, they will become more extensively used in the setting of priorities.

Predicting the probability of success in kidney transplantation is really only one-half of the problem in deciding priorities. The other half involves assessment of the risks and benefits of the other treatment available for the preservation of the life of the person with chronic renal failure, and that is dialysis in its various forms. Here we have not yet advanced quite as far as we have in transplantation because our data are not as yet detailed. On the other hand, the data are quite comprehensive. They are, indeed, national in scope, so that we can describe with confidence the outcome of dialysis, at least in terms of mortality, for the Nation as a whole. However, we cannot go beyond age, race, and sex in evaluating what factors have an important impact on mortality on dialysis.

In summary, we do not at this time possess more than the most rudimentary system of priorities for the allocation of available organs to patients awaiting transplantation because we lack data of sufficient breadth and detail to permit us to determine with certainty the outcomes in terms of mortality, morbidity, disability, or in general quality of life, both in the absence of and following transplantation. We also lack such data of sufficient breadth and quality to ascertain which patient characteristics and which subsidiary medical practices make outcomes most favorable both in the absence of and following transplantation.

On the other hand, satisfying advances are occurring in the field of the analytical techniques needed to make most effective use of such data. I anticipate that once such data become available, we will be able to make rapid progress in determining priorities.

Thank you.

[The prepared statement of Dr. Krakauer follows:]

TESTIMONY
of

DR. HENRY KRAKAUER
of the
NATIONAL INSTITUTE of ALLERGY and INFECTIOUS DISEASES
NATIONAL INSTITUTES OF HEALTH

before the
SUBCOMMITTEE on INVESTIGATIONS and OVERSIGHT
of the
COMMITTEE on SCIENCE and TECHNOLOGY

U.S. HOUSE of REPRESENTATIVES

on

ALLOCATION of HUMAN ORGANS for TRANSPLANTATION

NOVEMBER 7, 1983

The information that I shall present today is based not on personal, direct experience with the practice of transplantation but on the overview that I obtained as a former Chief of the Genetics and Transplantation Biology Branch of the National Institute of Allergy and Infectious Diseases (NIAID). In that role, I was responsible for the administration of grant and contract supported basic and clinical research on the immunologic processes that determine whether a graft succeeds or fails, and for the development, acquisition, and distribution to tissue-typing laboratories in the U.S. and overseas of reagents for histocompatibility testing, i.e. for determining the extent to which the currently recognized transplantation antigens of donors and recipients match. In addition, I have performed analyses to determine what patient characteristics and medical practices are associated with success or failure in kidney transplantation, using data collected by the NIAID and by the South Eastern Organ Procurement Foundation (SEOPF), and of the relative efficacy of dialysis and transplantation as treatments of chronic kidney failure, using data collected by the Medical Information System of the Health Care Financing Administration (HCFA). The results of these studies were published only very recently. I am prepared, in my testimony, to address technical issues, but am not qualified to discuss matters of policy.

Ideally, priority in the allocation of organ grafts should be based on an assessment of which potential recipient will benefit most. This requires knowledge of who is at highest risk of death and/or disability without the graft, and whose prospect of survival and return to useful activity following receipt of the transplant is the best. Unfortunately, both aspects of this problem are highly complex, a consensus has not been achieved on either, and there is no generally agreed-upon system for the allocation of organ grafts at this time. Because much medical information on the treatments of end-stage renal disease has been and continues to be collected, and adequate methods for analysis of the data are beginning to be applied, useful measures of the utility of the treatments for various persons are becoming available. Before I describe what we have learned that might be of use in the setting of priorities, I should indicate where matters stand now.

There are nearly 40 independent organ-procurement/organ-sharing agencies in the U.S. The largest of these, accounting for over half of the transplantable tissue shared, is the South Eastern Organ Procurement Foundation (SEOPF). In addition, SEOPF manages the United Network for Organ Sharing (UNOS). Together, these organizations maintain a list of, currently, over 5,000 persons with chronic kidney failure who are awaiting a transplant from a cadaveric donor.

When an organ is recovered and offered by a center in the SEOPF, it is matched against the list of potential recipients. Recipients who are incompatible with the donor because they have antibodies to the donor's ABO blood group antigens or to the donor's major transplantation (HLA) antigens expressed on white cells (leukocytes), as determined in a cross-match test, are automatically excluded. The remainder are ranked in the following order: (1) highly sensitized persons, i.e. who have antibodies against the leukocyte antigens of a large proportion of the population, take precedence over less broadly sensitized patients; (2) within this category, recipients better matched with the donor in terms of the major transplantation antigens, HLA-DR,B,A, are given higher priority; and (3) other things being equal, institutions in closest proximity to the harvesting center are ranked first. Medically urgent need by the recipient can override the above priorities. In addition, priorities based on the level of HLA-A,B,DR match are dispensed with when cyclosporin is used for immunosuppression. This system of priorities is not mandatory and kidneys are transferred on the basis of consultations between the transplant coordinators of the donor and recipient hospital centers. (E. K. Spees, et al., Heart Transplantation, Vol. 2, pp. 212-218, 1983).

The New England Organ Bank (NEOB) has a similar but somewhat more rigidly defined system of priorities. Of the two kidneys recovered from a cadaver donor, the harvesting hospital has first priority for one kidney, although it may choose or may be asked to release it. Sharing of released kidneys is determined by the following descending order of priorities: (1) Medical urgency (absence of access sites for hemodialysis or other threat of imminent death). (2) High levels of sensitization as determined by cross-matching against a panel of leukocytes. (3) Sharing of both HLA-DR antigens with the donor, if the recipient is not broadly sensitized. (4) Absence of HLA-A,B incompatibility. (5) NEOB net credit/debit rating for organ sharing by the recipient hospital. (6) Kidneys not placed within the NEOB institutions are offered to UNOS. Again, blood group incompatibility with the donor and presence of antibodies to donor HLA antigens in the serum of the recipient are disqualifying. The Tissue Typing Laboratory, a central facility, allocates the available kidneys. (NEOB Procedures Manual)

Organ sharing in Europe is more highly structured. In the United Kingdom, the controlling organization is the UK Transplant Service (UKTS). Potential recipients, not incompatible with the donor in terms of the ABO blood groups, are ranked in the following descending order of priority: (1) Membership in the National Health Service. Non-members, e.g. aliens, are given low priority. (2) Clinical urgency, i.e. death imminent unless a transplant is performed. (3) ABO blood group identical to that of the donor. (4) (a) Absence of HLA-DR mismatch, (b) absence of HLA-B mismatch, (c) absence of HLA-A mismatch. (5) Level of sensitization. In the absence of HLA-A,B,DR mismatch with the donor, the more broadly sensitized recipients are given priority, but the reverse is true if a mismatch has been identified. This last is the result of the absence of direct testing of the serum of the recipient against the leukocytes of the donor (donor-specific cross-match), a major difference with U.S. practice. (6) In the future, hospitals with longer waiting lists will be given priority. (7) If several potential recipients with equal priority remain, one is chosen at random.

Eurotransplant is a voluntary but very tightly run association of transplant centers, located in the Netherlands, Belgium, Luxembourg, Austria and West Germany. It has a waiting list of about 4,000. By agreement, all recovered kidneys are offered to Eurotransplant. Its system of priorities is quite complex. Matching of HLA antigens, especially the DR antigens of donors and recipients, is considered very important, but this can be overridden by clinical urgency, i.e. high probability of death within weeks unless transplanted. Highly sensitized patients are also given precedence, as are recipients with the same blood group as the donor, especially if it is O.

In these systems of priorities, there is complete consensus on ABO blood group incompatibility and a positive donor-specific cross-match (at least for antigens expressed on T cells) between donor and recipient as definite contraindications to transplantation because they are predictors of virtually certain failure. Because it is difficult to find a cross-match negative donor for a highly sensitized recipient, when such a donor is found, the recipient is given a higher priority for the organ. Clinical urgency as a determinant of priority is self-evident, but it is narrowly and specifically defined. The only criterion related to the probability of success of the transplant in other than an all-or-none fashion is the HLA match. Unfortunately, the evidence for the validity of this criterion in the case of cadaver-donor transplants is not very clear. However, HLA matching of related donors and recipients is extremely important. For example, on the basis of our experience prior to the advent of cyclosporin and donor-specific transfusions, the probability of retaining a functioning graft for at least one year could be as high as 96% for otherwise low-risk recipients if the HLA-match with the related donor was complete, but very much lower, approaching that expected with a cadaver-donor graft, if the donor and recipient were not so well-matched. By contrast, in the study conducted by the NIAID, the outcome associated with low degrees of mismatching (one or no HLA-A,B antigens) in transplantation with kidneys from unrelated cadaveric donors was slightly better, but not at a statistically highly significant level, than that associated with higher degrees of mismatching. The data collected by the SEOPF, however, suggest a larger and more significant detrimental effect of mismatching, a decrease of 1-year graft retention rates from 59% to 50%. Nevertheless, both studies identified other patient characteristics more highly predictive of outcome than HLA-A,B match, but which are not used at present in the setting of priorities in the allocation of cadaveric grafts. These include, for example, diabetes as the cause of initial renal failure, rejection of a prior graft, and high levels of sensitization as predictors of a reduced probability of success (H. Krakauer, et al. Transplantation, Vol. 35, pp. 372-378, 1983).

Data such as these make it possible to predict probable outcomes of transplantation in prospective recipients, and therefore should give substantial assistance in clinical decision-making. Their validity, however, is critically dependent both on the absence of biases in the information collected and on the adequacy and appropriateness of the methods used for analysis. The two studies mentioned previously, that of the NIAID and that of the SEOPF, were both very large, each involving about 1500 cadaver-donor transplants. Nevertheless, there were large systematic differences in the populations investigated and in the medical practices used which resulted in the absence of concordance on certain prognostic factors. Such systematic differences have been termed "center effects" and are the source of much controversy in the medical literature. Most recently they have seriously complicated assessment of the utility of matching of HLA-DR antigens in improving the success rate of transplantation. Several centers in the U.S. and Europe have reported a very highly beneficial effect of such matching and some have not. The one major multi-center study, carried out in conjunction with the 8th International Histocompatibility Workshop indicated significantly higher graft survival associated with better HLA-DR matches only in individuals who had not received pre-transplant blood transfusions.

To this point, I have only addressed the problems associated with the identification of factors that affect the outcome of transplantation. Similar problems exist in assessing the utility of the various forms of dialysis as treatments of end-stage renal disease.

In summary, we currently have insufficient data on histocompatability and related aspects necessary to further determine criteria for the allocation of organ grafts. Also, better methods of analysis must be developed. Much remains to be done before a consensus on the choice of treatments and the allocation of priorities for limited resources in achieved. Moreover, because of the constant and rapid evaluation of medical technology and practice, these efforts should be on-going.

This concludes my statement, Mr. Chairman.

Mr. GORE. Thank you very much.

Well, this is all very, very interesting.

Let me start with you, Dr. McDonald. You made a statement in your testimony which it seems to me strikes very close to the heart of this issue. You said that you, in your institution in Louisiana, decided that you would not accept nonimmigrant aliens as patients. Now, the reason you gave was that you felt if you had a nonimmigrant alien on your waiting list, you would sooner or later end up giving an organ to that patient instead of to an American patient outside of Louisiana; is that right?

Dr. MCDONALD. Yes, that was my reasoning, Congressman.

Mr. GORE. Now, that provokes several questions. First of all, the threshold question is, do you think that American citizens ought to be given a priority, all other things being equal, or even slightly tilted against the American citizen?

Dr. MCDONALD. I think that's a very complex question, and obviously there are many ways to look at it. I think in all honesty, Mr. Gore, one of the reasons we chose simply to not get into that was because we didn't know what the right answer was, and we just wanted to say we're just not going to do that and then I won't have to defend in some congressional hearing as to why I put one kidney in some person and not in someone else. Because I don't know the answer to it.

Mr. GORE. Well, you have answered it, though. I mean, you have answered it in practice——

Dr. MCDONALD. Well, I think it is clear—I think it is clear that if I have *x* number of patients in my local list, and they are all American citizens, that if I don't have someone that can accept a kidney or an organ that I retrieve, I will share it.

Mr. GORE. Yeah.

Dr. MCDONALD. And that will go more than likely into another American citizen. If I have a group of nonresident aliens, they're going to take up kidneys that I would ordinarily have shared with other institutions. I think that just has to happen.

Now, whether or not that's good or bad is a different question, and my thought is that there are an awful lot of American nationals that need kidneys. I guess I did not want to go a whole lot further than that.

Mr. GORE. So what you're saying is that you passed on the bioethical question and decided on the political question, essentially. You felt that—not political in the electoral sense—but you felt that strong feelings would be aroused by a contrary policy, and the bioethical question was so difficult, and you weren't sure of the answer to it, you felt it would just be easier to stay out of it.

Dr. MCDONALD. Well, that's in part so. But perhaps that's too simplistic. I have in my own practice, and in my own efforts within the field of transplantation, been committed to the concept of organ sharing, that there is a place for it and it is proper to share organs from center to center and have been actively engaged in the question of establishing that you may do that. There have been arguments among the professionals as to whether or not you are better off to take a kidney that you obtained—you know more about it, you can testify about its integrity—that it's perhaps better to put that organ that you know is good into your own patient with a lesser degree of compatibility, for example, than to accept a kidney from another institution harvested by other people, in which you have less absolute knowledge as to the quality of that kidney. It may be that their kidney has been sufficiently damaged that, even with a slightly better match, the patient is not benefited. The patient could be harmed.

So we have been interested in establishing that you can share kidneys with equal or better outcome, and I guess perhaps my commitment to organ sharing prejudices me against that course of action, also.

Mr. GORE. Now, the second line of questions opened up by this example is this policy, which seems to be quite widespread, of looking first to the medical center within which the organ is harvested, next within the same city or State. You said, Miss Peele, that your policy at St. Luke's is Illinois first. At Rush Presbyterian the policy is Illinois first. That is quite common, it seems to me. But I want to question that. I want to question that, on several grounds.

First let me give you a hypothetical, Dr. McDonald. If you have a slightly better match in Arkansas—let's say you've got a patient in Texarkana instead of in Shreveport—why should the patient in Shreveport get priority?

Dr. MCDONALD. I don't think he should get priority, provided you have sufficiently factual reason to know that the patient in Texarkana is more likely to accept the graft than the one in Shreveport. But Dr. Krakauer has just provided you with information that the basis upon which you select who is going to be the final recipient is arguable among scholars in the field, and some people take the view that—there are some centers who, according to local regulations, will place a kidney into any recipient as long as the cross match is negative and they believe the kidney is in good health. My own center will not—I will not transplant kidneys into patients who do not have at least a two-antigen match. So that by virtue of that, we commonly have kidneys that we cannot put in our patients, and therefore we share. Other institutions with a different attitude would use all of the kidneys that they procure and would share very few.

Mr. GORE. But——

Dr. MCDONALD. But I think—I'm sorry, but I think that there is merit in allowing the local organization to set its own guideline, and I would like to give you an example.

If we established a certain set of guidelines, then the individual institution who has a new idea, or a new concept, of how to improve things, may be locked into a set of criteria that it cannot get away from. I think that may not be in the best interest of the science.

Some 3 or 4 years ago, or prior to some 3 or 4 years ago, for example, the University of Pittsburgh, part of the SEOPF group, used to share a large number of kidneys. When they started their study with cyclosporin, they wanted to test out that drug, and in the past 2 or 3 years have not shared many kidneys because they have put more less-compatible grafts into their recipients to treat with that drug. They, therefore, have altered their local guidelines and I think we're all better for it, because within 1 year or 2 we're going to know the answer to that.

Mr. GORE. But that's a different question. I mean, that's really a different question. What I'm getting at is the common policy of looking first to the same medical center and then to the same State. I mean, it seems to me that that's really got to be questioned.

I got a letter the other day from—it was actually sent to someone else and a copy of it was sent to me—about a family whose daughter had experienced brain death. The transplant coordinator approached them, they were very complimentary of the way the coordinator had approached them and convinced them to make the organs available for donation.

About 3 weeks later, one of the doctors caring for their daughter happened to mention routinely that they were giving a drug to help sustain a heart function because there was not yet a suitable recipient within that State, and the persons who would harvest the organ were not ready to get it yet because there was no recipient in that State. There were recipients in other States.

Well, the family said to cut off the machine. They were willing to make the donation available, but here they waited for 3 weeks, and it seems to me that that's yet another problem that can come up by just looking within the same medical center or within the same State.

Do you want to comment on it?

Dr. MCDONALD. Well, I would certainly join you in decrying that action. But I think that must be a relatively unique and rare circumstance because when we have kidneys——

Mr. GORE. This was a heart.

Dr. MCDONALD. Well, whatever the organ is——

Mr. GORE. But, you see, part of the problem is the system that started for kidneys is now being used as the prototype or model for all of these other organs that are becoming available for transplantation. And the assumptions upon which the kidney procurement system is based really have got to be looked at closely. One of them is this.

And the reason it comes up is this is precisely the reason why nonimmigrant aliens are said to occasionally get preference over Americans. You said you decided not to put nonimmigrant aliens on your waiting list because you knew that your preference for patients within that area would eventually lead you to transplant a nonimmigrant alien before making the kidney available to an American outside of that geographic area. So the driving principle, the driving force, is preference for first the medical center, and second the small geographic——

Dr. MCDONALD. I have already testified that I have spent a good deal of my life trying to stimulate organ sharing——

Mr. GORE. Oh, I'm not criticizing you, Doctor, please——

Dr. MCDONALD [continuing]. And I'm not in a position of defending the lack of organ sharing. But I would like to say that you cannot separate the physician's attachment to his patient from his function as a humanitarian and on ethical grounds.

Now, if he has 75 patients on his own waiting list and he knows them, and he sees them every week or every month, he gets more attached to them, and you cannot I think tell him that he cannot use judgments and you can't keep him from allowing his emotions to interfere with that. I suppose it would not be unlike the fact that, although I'm sure you represent the Nation as a whole, you have your own constituency that you have some special concerns for.

Mr. **Gore**. Sure.

Dr. **McDonald**. I think that that's not unreasonable.

Mr. **Gore**. And I have a constituent who could have used that heart in the State of Florida.

Dr. **McDonald**. Sure. And he should have had it.

Mr. **Gore**. She, in this case.

But Professor Reich on the first panel spoke about responsibilities as well as the bioethical concerns, and I think that is really what you're getting at. It's not just a question of emotions that the doctor feels toward the patients that he or she has been taking care of; the doctor also has a medical responsibility to those patients. You see, this really sharpens the conflict on the nonimmigrant alien issue. You all—and again, let me insert parenthetically, I didn't mean to imply any criticism at all. What you have done is fabulous. I'm using your example as a way to illuminate some of these bioethical issues that are very tough for me to grapple with. But it does—it just seems to me, in wrestling with these issues, one of the things that we have to examine more closely is this regional preference.

Let me ask Amy Peele, who trains coordinators all over the country—and you have really devoted your life to this—how do you defend an "Illinois first" policy?

Ms. **Peele**. How do I defend it?

Mr. **Gore**. Yes.

Ms. **Peele**. In other words, when we recover a kidney locally, why we give preference to our Illinois residents?

Mr. **Gore**. Correct.

Ms. **Peele**. It's standards that are set by the transplant surgeons in our community that we abide by, and that we try to place them locally first because again, as Dr. McDonald said, these surgeons know their patients. We have a lengthy waiting list locally of 500 to 600 Illinois residents waiting for a kidney, and so we try to match it with those patients before we would send that kidney out of Illinois.

Mr. **Gore**. Well, I mean, again, the first place you look is in your own institution, right?

Ms. **Peele**. That's correct, unless there's a patient outside our institution that's highly sensitized and that has a negative cross match and can accept that kidney within Illinois, then they will get first priority.

Mr. **Gore**. So a nonimmigrant alien within your own institution would get preference to an American citizen across the State line?

Ms. **Peele**. No. According to our priority lists that I included in my testimony, the nonimmigrant alien is listed at the lowest priority, No. 9 of getting a kidney, a kidney procurred in Illinois.

Mr. **Gore**. Well, but No. 9 within the State, right?

Ms. **Peele**. That's correct.

Mr. **Gore**. And if you have a nonimmigrant alien that is in the institution, and there is an acceptable match, you will go ahead and transplant that nonimmigrant alien before looking to Indiana, right?

Ms. **Peele**. That's the decision that is made by the surgeons within Illinois.

Mr. **Gore**. And that is the decision they have made, correct?

Ms. **Peele**. That's correct.

Mr. **Gore**. So if you have two cases, and there's an acceptable match in both cases, the nonimmigrant alien will get preference by virtue of the fact that the nonimmigrant alien is located within a specific geographic area?

Ms. **Peele**. I think you can make that—

Mr. **Gore**. I mean, that does seem to be the case. And it's ironic because the policy of, say, "Illinois first" is, in microcosm, a reflection of the policy "Americans first." I mean, the same kinds of dynamics are at work in both places. It's interesting that the policy of a particular State first would operate to override the policy of "Americans first."

Dr. Terasaki, do you want to comment on this? You don't have to if you don't want to. All right.

Now, Dr. McDonald, how do you react to Dr. Krakauer's statements that the current criteria we're using to determine who ought to get a higher priority, medical criteria, are just not very good compared to other criteria, far more predictive of the outcomes that are not being used?

You heard his statement. How do you react to it?

Dr. **McDonald**. I'm not sure I understand the implication of your question, Mr. Chairman. I agree basically with what Dr. Krakauer has said, in terms of the fact that presensitization is a principal determinant. I agree with Dr. Terasaki that the highly sensitized patient is a principal determinant.

I feel a little more confident in the data that indicate that tissue typing is a major determinant than Dr. Krakauer has implied, and that's basically because I think in science, when you have data that show something positive, that's more important than data that don't show anything. There are a number of studies that do support tissue typing as a basis of organ sharing, and I'm inclined to believe them. But I do agree with them that there's a great deal of argument about that.

But I do not think, if you're implying that you should select diabetics, or you should delete diabetics, from receipt of grafts, as opposed to nondiabetics, because you know that the diabetic has a higher mortality rate than the nondiabetic, you could make that case if you were ethically committed to the kidney; that is, if you had a kidney and you said I'm going to do what I can do that is best of all to see that this kidney works for a long time, you could then say I will not transplant diabetics because they have a higher mortality rate and the patient will more likely to die and I'll lose the kidney.

But the point is that doesn't work when you're dealing with the patients because the diabetic patient has a much higher incidence of death on dialysis, just like he does from transplantation. So that even though yes, more of those patients are going to die, but they're in worse trouble and therefore you can't use that parameter to select whether or not that patient is going to get a kidney or not—if that's the implication of your question.

Mr. **Gore**. OK. Did you want to comment, Dr. Krakauer?

Dr. **Krakauer**. That is really precisely the point of my presentation, that we do, in allocating grafts, need to take into account the relative risks of the alternatives that are available to us. A patient who is likely to do well on dialysis and poorly with a transplant should not be transplanted; someone who is likely to do poorly on dialysis and not as poorly with a transplant should be transplanted.

I specifically investigated that issue of excluding from transplantation persons who are at high risk of graft rejection, and my conclusion was that such an exclusion would be a counterproductive policy. The end result, in fact, would be sentencing several thousand people to death who would otherwise have been alive with a functioning graft.

Mr. **Gore**. Dr. Feduska, do you want to comment on this? How do you react to his findings?

Dr. **Feduska**. Well, this is obviously a very complicated issue, but I think it is important to point out, with all due respect to Dr. Krakauer's study and some of the other studies that have been reported, that those factors which can positively influence the outcome of a cadaver transplant are rather limited in number. For instance, while there are some studies suggesting that the quality of match between the donor and the recipient does have some effect, there are many other studies that do not show that relationship.

For example, in our own experience, with almost 1,400 cadaver transplants, as we analyze our own data, looking at the quality of match relative to the success rate of the transplants, there is no difference. A transplant in which there is no antigen similarity between the donor and the recipient has as good a chance of being successful over time as does a transplant in which the quality of match is very good.

There are other factors, however, and the most notable in our own experience, and that of many other centers, is the role of blood transfusions given prior to the transplant itself. These are factors—blood transfusions as an example—that can be controlled locally. It is possible to prepare patients as candidates for cadaver transplants by transfusing them.

And so I think, in my own mind, that the scientific justification at the present time—and hopefully this will change in the future—but the scientific justification today for sharing of kidneys, cadaver kidneys, among different centers, trying, for instance, to achieve a better quality of match, is still highly questionable. And some other factors such as pretransplant blood transfusions, rather convincingly in most studies, have a very profound effect. I think that this kind of data justifies approaches such as we have in our own center, where we do, in fact, consider our own patients first, preferentially, rather than considering patients elsewhere in other geographic locations. I think this is justified because my own bias is that transplantation is a very complicated activity. There are many very important technical variables and other variables involved with regard to the quality of the donor, the quality of the kidney, how the kidney is removed, how the kidney is preserved, and I believe that what is more important than some of these other factors is the quality of the organ itself. And the manner in which we have tried in our own center to control this is by involving members of our own specialized team in selecting the donors, making sure that they are truly acceptable, managing them so the quality of kidney function is optimal, removing the organs so they are removed properly with a low incidence of avoidable complications, and then preserving them by methods that we know to be reliable.

So I think there is justification for using the kidneys locally preferentially.

Mr. GORE. Well, wouldn't that result in a greater effort to obtain organs for transplantation, when you've got a need within your own institution, and then falling off in the efforts when there is nobody waiting within your own institution?

Dr. FEDUSKA. Well, I agree, yes, this does provide a very potent stimulus to get involved in developing effective cadaver organ donor programs. The point is, however, that virtually all transplant programs in this country have a deficiency of organs; there are more patients waiting than there are kidneys available.

Mr. GORE. And there are more potential donors that could donate than there are patients waiting for——

Dr. FEDUSKA. Precisely.

Mr. GORE. Yeah.

Now, when you say that—I don't want to get away from this point you just made. You offered a justification for looking to your own institution first, and basically that justification is that you know more about the donor?

Dr. FEDUSKA. Well, the justification I believe is that the factors which we know to significantly influence the outcome of transplants can be controlled locally within your own patient population, to a degree.

Mr. GORE. And what factors are those?

Dr. FEDUSKA. The most significant is that of pretransplant blood transfusions.

Mr. GORE. Why couldn't that information be shared as a blood type is shared?

Dr. FEDUSKA. It can be shared.

Mr. GORE. Well, then, it would be equal from institution to institution.

Dr. FEDUSKA. Well, it would. But the point is that if one were to consider this factor predominantly, then the likelihood is one would have such a patient available for the transplant within his own center and would not have to look elsewhere to find a suitable recipient.

Now, I think perhaps——

Mr. GORE. Wait a second. If you know—Let's say that we get agreement on what factors are predictive of outcome and which factors are not predictive, OK? Then let's say that we have got a set of, a limited set of factors, four or five, that we accept as predictive. And then you have got, according to those factors, a higher degree of success outside your institution for a given organ than inside.

Would you still give preference to the patient inside your own institution?

Dr. Feduska. No, I would not.

Mr. Gore. OK.

Dr. Feduska. The science of transplantation today is still historically young, and I'm sure that as time goes on a lot of these considerations are going to become clarified. But the water is still a bit muddy today.

Now, the alternative approach would be to develop transplantation in such a fashion that there would be regional centers doing larger volumes of activity than is the case presently. There are many transplant centers in this country today doing small numbers, and there are some doing large numbers.

Mr. Gore. Well, that's, of course, what we're pushing toward and what most people who have looked at this agree makes sense for new technologies.

What justification is there for giving priority within an individual State?

Dr. Feduska. Well, I'm not sure there's justification for giving any particular priority within a given State——

Mr. Gore. But it happens. It happens.

Dr. Feduska. Well, I——

Mr. Gore. Amy Peele has testified—and it's not confined to Illinois; it's true in Louisiana, isn't it, Doctor? It's not? Is it true in California?

Dr. Feduska. It is not true in California.

Mr. Gore. In southern California?

Dr. Feduska. Dr. Terasaki could answer that question.

Mr. Gore. Dr. Terasaki, is it true in southern California?

Dr. Terasaki. Mr. Chairman, we do try to transplant within southern California, but when we go outside of California, we would consider the whole country.

Mr. Gore. Well, OK. But let's stay inside Illinois and southern California, for example. What justification is there for giving a priority to a patient within southern California? It's outside of your institution, but it's within southern California.

Dr. Terasaki. Yes. What I would like to do is think about why we should share at all. In other words, you're saying that we should send kidneys to someplace else. And Dr. Feduska has just mentioned that without sending kidneys, especially, for example, in San Francisco, they can get very good results just locally.

We think that most of it depends on tissue typing, whether you think that tissue typing is important or not. Tissue typing has some problems and there isn't general agreement as to whether it's important or not. This is the reason why there is variance in the policy of sharing kidneys.

Mr. Gore. Well, let me read you the guidelines from your regional organ procurement agency, of which you are president. This was supplied to us by Dr. Robert DiMendez, who is the director of renal transplantation at St. Vincent Medical Center. He is with your regional organ center, right?

Here is the policy: "Of two organs retrieved, one is kept for the use of the procurement team, and the second is given up to a pool within the regional organization to be given to the best matched individual in that area. If it is not wanted by anyone in the southern California area, then it is shared in the Western Association transplant surgeons sharing region to the best possible match." Then, if there is no one in that area, then it is made available to the rest of the country.

First of all, why would you make available only one of the two kidneys instead of both?

Dr. TERASAKI. Well, it is important to understand the history of all of this. Initially, that was the rule, that if a kidney is obtained at one hospital, it stays there. That's the first priority. We have gradually moved from that kind of priority to a situation where we do share kidneys within the Los Angeles area. And actually, today we do share both kidneys on the basis of HLA-DR matching. So HLA-DR matching is the first priority within the Los Angeles area today.

With regard to the WATSS, this is a loose organization. We——

Mr. GORE. Wait a second, wait a second. Maybe I'm just not understanding clearly.

Tell me again why only one is shared?

Dr. TERASAKI. No, both kidneys are shared——

Mr. GORE. Both are shared?

Dr. TERASAKI [continuing]. On the basis of DR matching.

Mr. GORE. Pardon me?

Dr. TERASAKI. This is a policy that we changed in January of this year.

Mr. GORE. Oh. So now both are shared as of this year?

Dr. TERASAKI. Yes.

Mr. GORE. OK. Well, why is southern California given—In other words, if you have a better match in northern California, somebody in southern California gets preference over a better match in northern California.

Dr. TERASAKI. Yes. The main reason is that the question of whether a kidney does better in a matched patient or not is the question. As you just heard from Dr. Salvatierra, he is transplanting all the kidneys, matched and mismatched.

Mr. GORE. Well—but wait a minute, now. You can't tell me that these scientific criteria are useful for purposes of assigning priorities within the region, but they're meaningless when it comes to deciding outside the region. That, it seems to me, is what you're telling me.

Dr. TERASAKI. Yes. The situation in tissue typing—and this is the main area that I have been working in for 25 years—is that we still, after 25 years, do not have general agreement on what is the best match and what matches we should completely avoid.

Mr. GORE. But this guy in northern California is going without a kidney because of what appears to be—and I don't want to sound harsh—but what appears to be a chauvinistic preference for the geographic area within which one is located.

Dr. TERASAKI. Yes. Well, in northern California they have a group of patients that they are trying to transplant. They have an excess of patients, something like 400 patients. In southern California we have around 200 patients that we are trying to transplant. So generally, within each area, as Dr. McDonald mentioned, people are trying to get those patients transplanted. We have no reason to send it to San Francisco if there is a reasonable match in Los Angeles.

Mr. **Gore**. Let me read you the priority list for New England, the priority system for kidney distribution with the New England Organ Bank:

Kidney No. 1, the harvesting hospital gets first priority, regardless of ABO. Even if there—I mean, without—even if it's a different blood type, the harvesting hospital gets first priority regardless.

The second kidney down at the national system is down at the bottom of a list of six priorities.

Let me ask you, Dr. Feduska, is this common around the country? California just changed it this year. New England, I think, still has it, that the hospital that harvests the organs keeps one, no matter what?

Dr. **Feduska**. Well, I think this is not an uncommon practice, but what I would like to say is that the influence of some of these considerations on the ultimate success rate of transplants is not firmly established, the influence of the quality of match between the donor and recipient on the success rate of the transplants. Some of the factors that we have identified to have an influence have been identified by looking at large pools of data retrospectively. Scientifically, that's always a somewhat dangerous thing to do.

I think there is a place for sharing organs in this fashion with the idea that one will selectively and prospectively match the organs with individuals who may be of a very excellent match, or possibly even a poor match, trying to answer the kind of question that we're not prepared to answer unequivocally for you today.

Mr. **Gore**. OK. The sum total of what you're telling me on this point is that the medical criteria demonstrating what is a good match and what's a bad match, those criteria will not support a decision to allocate an organ outside of your geographic area, right?

Dr. **Feduska**. Today I believe that's the case. Some of the criteria are rather arbitrary.

Mr. **Gore**. OK. Now, those same criteria are being used today to allocate organs to nonimmigrant aliens on a priority basis over American citizens, within the same geographic area.

Now, if they will not support a decision to allocate to an American citizen in another geographic area, how can they be held up as the bedrock of bioethics to support an allocation to nonimmigrant aliens over American citizens within a geographic area?

Dr. **Feduska**. Well, as I was saying earlier in my testimony, the practice in our own center is to give first priority consideration to patients who were U.S. citizens. However, this whole issue is much more complicated, I think, than many people realize. In spite of our present waiting list——

Mr. **Gore**. I don't think anybody would disagree with that at this point. But go ahead.

Dr. **Feduska**. In spite of our present waiting list, for instance, of 454 patients, the number of different variables involved is such that it is not at all uncommon for us to have two suitable kidneys available for transplantation and from that list of patients to have a remarkably small number of patients who at that time are compatible with the donor by accepted methods of tissue typing and who, by other criteria, are optimally or even sometimes perhaps less optimally suited to receive those organs. The size of the waiting list is somewhat misleading because many of the patients on the waiting list have certain features which we know will make it exceedingly difficult to find a compatible transplant for them. So that in a more practical sense, the list is much smaller.

And then one gets into the logistical difficulties of working with a larger pool of patients over very large geographic regions, and some organizations, as you have heard, have attempted to do that. But it hasn't been practiced everywhere.

Mr. **Gore**. You say on page 4 of your prepared statement:

> In spite of the large number of candidates on our waiting list, consideration of these multiple factors during the process of selection frequently results in the identification of only a small number of patients who are optimally suited to receive the transplants. It is in such circumstances that non-resident alien patients have a greater possibility of being selected.

Why?

Dr. **Feduska**. Well, it's because of a number of factors. As an example, the amount of time required to establish, for instance, that on our own waiting list that we do not have a suitable recipient available who is a U.S. citizen, is such that the duration of preservation has already reached the point where it may not be logistically feasible to share that kidney with some other center, particularly a center with which one does not already have an established relationship, so that the patients in that other center have already been studied against that potential donor as well.

Mr. **Gore**. Lack of coordination, lack of a national system——

Dr. **Feduska**. Precisely.

Mr. **Gore** [continuing]. That's capable of factoring these things into the decision, right?

Dr. **Feduska**. Exactly. And I think clearly some of the proposals that you have made are going to be very significant in helping us with this problem. But it is a problem.

Mr. **Gore**. Evidently, evidently. I have to agree.

Now, Miss Peele, in your institution a large number of Greek patients are transplanted or used to be, in any event; is that correct?

Ms. **Peele**. What do you mean by "large"?

Mr. **Gore**. Maybe I'm misstating it. How many, roughly? You tell me. I'm not sure.

Ms. **Peele**. I think in the testimony I said that 1981, 1982, and 1983 we had done 18 transplants each year, and in 1983 we had done 38. And to date, of those 3 years, 5 nonresident aliens had been transplanted.

Mr. **Gore**. Well, that's not what I would call a large number on a percentage basis. One could quarrel with the definition of the word.

But what I'm leading up to is this: Are you aware of any programs to actively solicit nonimmigrant aliens abroad to come to the United States for transplantation, either now or in the past?

Ms. **Peele**. Programs or doctors?

Mr. **Gore**. Doctors.

Ms. **Peele**. Yes.

Mr. **Gore**. You're aware of doctors soliciting patients from overseas?

Ms. **Peele**. Yes

Mr. **Gore**. Now, is this still going on?

Ms. **Peele**. I don't know.

Mr. **Gore**. OK.

Without objection, I would like to put into the record the translation of a pamphlet that has come to the subcommittee's attention from Rush Presbyterian-St. Luke's Medical Center, or more accurately—I guess it's not from the medical center. It is from a Dr. Frederick Merkle.

Now, he has operating privileges at the center; is that correct?

Ms. **Peele**. That's correct.

Mr. **Gore**. And used to be director of transplantation?

Ms. **Peele**. That's correct. The section was dissolved about a year and a half ago.

Mr. **Gore**. OK. I'll let the translation of this pamphlet speak for itself in the record.

But let me ask you generally, are you familiar with the pamphlet that I'm referring to?

Ms. **Peele**. I've seen it, but it's in Greek and I don't read Greek.

Mr. **Gore**. Well, that's why we're going to put a translation in the record. But we are informed that it is distributed within Greece and has served as the basis for patients coming from Greece to Rush Presbyterian in Chicago for transplantation.

Are you aware of patients—you are aware of Greek patients that have come to Rush Presbyterian; presumably you don't know whether or not it was as a result of this pamphlet?

Ms. **Peele**. Yes, they came to Rush through the private practice.

Mr. **Gore**. Through the private practice. So they were referred to Rush by—from Dr. Merkle's private practice?

Ms. **Peele**. To the best of my knowledge.

[The pamphlet follows:]

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TRANSLATION OF LETTERS

Congressional Member or Committee H Science/Technology Comm Investigations/Oversight SUB

Language Greek

Material Submitted brochure

Date of Material

Name and Address of Sender

Suggested Salutation

Translated by Niove Kyparissiotis (name) Shared Cat. Div. (division) Processing (department)

Date May 8, 1984

☒ Complete ☐ Abstract--Please call the Congressional Research Service (426-5700), if a complete translation is desired.

Column 1

Beginning not clear for about one and a half lines.

The Presbyt [blank] is a University Hospital with an 873 bed capacity situated on the west side of the city of Chicago, and part of the biggest medical establishment in the world. The Rush serves a representative population, of various ethnic backgrounds including a large Greek community.

Dr. Frederick K. Merkel, assistant professor and Director of the Department of Transplantation is the main transplant surgeon in the hospital. Dr. Merkel was born in Greece.

In the transplantation group are included doctors, nurses, pharmacists, dieticians, and social workers of high scientific qualifications. This well organized group coordinates its activities towards one effort [and this is] to include the entire spectrum of medical care related to kidney transplants. This coordinated effort is the only way to guarantee that a [kidney] well chosen will secure for every patient an improved quality of life.

Discovering a donated kidney

A good transplantation program requires the selection of a suitable kidney for each case. It is important to know that kidney transplants from a living donor, a relative of the patient has a greater possibility for long term success than a kidney obtained from a cadaver. Consequently we recommend to patients who are candidates for a kidney transplant that they discuss the need with those close to them [sentence seems to continue but continuation does not appear in the next column]

Column 2

[blank, may imply "the patient"] waits, for finding a suitable kidney from one week up to a year and once in awhile perhaps even longer.

However, a transplant from a living donor can be programmed in advance so that, on the one hand the length of time related to hemodialysis can be limited and, on the other hand, the return of the patient to Greece can be expected within a reasonably short period of time. Each relative with the same type of blood as the patient can be considered as a possible donor. Included in the category of possible donors are parents, grandparents, sisters, brothers, half-brothers and sisters, nephews, cousins, uncles and children. The donor must not be over 65 nor younger than 15 years of age. In order to ascertain possible donors two blood tests can be done in Greece and the results can be communicated to us within a few days. After the selection of the donor, intensive work is required to ascertain that the health of the donor will not be impaired by the removal of the kidney.

Hospital care

A patient awaiting a kidney transplant from either a living donor or from a dead person, must be admitted in the Rush Presbyterian - St. Luke's Hospital for extensive preparatory work. Patients between the ages of 5 and 65 are eligible for a kidney transplant. Preparations are needed to avoid problems related to staying in Chicago for every patient who wishes to undergo a preparatory transplant examination in our hospital.

Column 3

[blank].... English and Greek. If this is necessary it can be arranged after arrival in Chicago. Preparatory operations may be considered as necessary and may require a prolonged stay in the hospital.

Preparatory dental examination is necessary but can be done in Greece. In such a case, the patients must bring with them the relevant x-ray pictures.

Cost of transplantations

During the time the patient is not in the hospital hemodialysis must be done in a hemodialysis center for out-patients. These centers require payment in advance from all the foreign patients. The patient needs three hemodialyses a week and an interpreter during the hemodialysis. Today the cost of each hemodialysis is $150.00, not including the cost of medicines, laboratory tests, or transfusions. When everything is ready for the transplantation the patient will have to wait in Chicago from three to six months until a cadaveric kidney is available.

After the transplantation, the patient must remain in Chicago three months after he is released from the hospital. During this period the patient will give blood for tests three times a week at the present cost of $50.00 each time. In addition the patient will be examined in our offices once a week.

Column 4

Many factors may interfere with the operation related to the removal of the spleen and with the transplantation itself so that the initially estimated expenses may present a significant reduction or increase depending on the actual condition of the patient and possible complications.

It is estimated that the preparatory work for the removal of the spleen costs today about $30,000.00 including the hospital expenses and the doctors' fees. This amount must be deposited before the patient enters the hospital.

As soon as the patient enters the hospital for the transplantation an additional amount of $45 - $50,000 must be deposited. It must be emphasized that these amounts do not include the expenses for hemodialyses done outside the hospital in doctors' offices, medications, transportation, and expenses for room and board.

Patients interested in transplantations can write to the Medical Center for more information, and we'll be glad to answer all your questions.

Our address and telephone number are:

Rush Presbyterian
St. Luke's Medical Center
1753 West Congress Parkway
Chicago, Illinois 60612
(312) 942-6242

Column 5

Personnel of the Clinic for transplantations
Department of General Surgery
Frederick K. Merkel, M.D.
Director

Πολλοί παραγοντες μποροῦν νά μεσολαβήσουν εἰς τὴν ἐνχειρησιν ἀφαιρέσεως τῆς σπληνός κα. εἰς τὴν μεταμόσχευσιν αὐτὴν καθ' ἑαυτήν, οὕτως ὥστε τά ἀρχικῶς ὑπολογισθεντα ἔξοδα νά παρουσιάσουν σημαντικη μειωσιν ἤ αὔξησιν ἀνάλογα μέ την παρουσαν καταστασιν τῆς ὑγειας τοῦ ἀσθενοῦς και μέ πιθανές ἐπιπλοκές.

Ὑπολογιζεται ὅτι ἡ προκαταρτικη ἐργασια μέ ἀφαιρεσι τῆς σπληνός στοιχιζει σήμερον περιπου τριαντα χιλιάδες δολλαρια, συμπεριλαμβανομένων τῶν ἐξόδων Νοσοκομειου και ἀμοιβῶν ἰατρῶν. Τό ποσόν τοῦτο θά πρέπει να καταβληθῆ πρό τῆς εἰσόδου τοῦ ἀσθενοῦς εἰς τό Νοσοκομεῖον.

Ἅμα τῆς εισοδου τοῦ ἀσθενοῦς εἰς το Νοσοκομεῖον διά την μεταμοσχευσιν θα πρέπει νά καταβληθῆ και το ἐπιπλεον ποσόν τῶν σαράντα πέντε μέ πενῆντα χιλιάδων δολλαριων. Πρέπει δέ νά τονισθῆ ὅτι εἰς τά ποσά αὐτά δέν συμπεριλαμβάνονται ἔξοδα αἱμοδιαλύσεων εἰς ἐξωτερικά ἰατρεῖα, φάρμακα, μεταφορικα, ἤ ἔξοδα διαμονῆς καί διατροφῆς.

Ἀσθενεῖς ἐνδιαφερόμενοι διά μεταμοσχεύσεις μποροῦν να ἀπευθύνονται διά περισσοτέρας πληροφοριας εἰς τό Ὑγειονομικόν κέντρον καί εὐχαριστως θά σᾶς ἀπαντήσωμε εἰς ὅλα τά ἐρωτήματα.

Ἡ διεύθυνσις καί ὁ ἀριθμός τηλεφώνου μας εἶναι:

RUSH PRESBYTERIAN
ST. LUKE'S MEDICAL CENTER
1753 WEST CONGRESS PARKWAY
CHICAGO, ILLINOIS 60612
(312) 942-6242

CLINICAL DEPARTMENT
OF TRANSPLANTATION
DEPARTMENT OF
GENERAL SURGERY

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FREDERICK K. MERKEL, M.D.,
Διευθυντής

STEPHEN C. JENSIK, M.D., Ph.D.

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PRES[redacted] είναι ένα Πανεπιστημιακόν Νοσομειον δυναμικότητος 873 κλινών, τό όποιον εύρίσκεται εις το δυτικόν τμήμα τής πόλεως τού Σικανου και άποτελεί μέρος τού μεγαλυτέρου εις τόν κόσμον ύγειονομικού συγκροτήματος. Το Rush έξυπηρετεί έναν άντιπροσωπευτικόν πληθυσμόν, ποικίλων έθνικων προελεύσεων, συμπεριλαμβανομένης και μιάς μεγάλης Έλληνικής κοινότητος.

Ό ίατρός κύριος Frederick K. Merkel ύφηγητής και διευθυντής τού τμήματος μεταμοσχευσεων, ό όποίος μάλιστα έχει γεννηθεί στήν Έλλάδα, είναι ό κυριος χειρούργος μεταμουχευσεων τού Νοσοκομείου.

Εις τήν όμάδα τών μεταμοσχεύσεων περιλαμβάνονται ίατροι, νοσοκόμοι, φαρμακοποιοι, διαιτολόγοι και κοινωνικοί λειτουργοι, ύψηλής έπιστημονικής καταρτήσεως. Αύτή ή καλώς όργανωμένη όμάς συντονίζει τάς ένεργειας της είς μίαν προσπάθειαν νά συμπεριλάβη όλο τό φάσμα τής ύγειονομικής περιθάλψεως τό σχετικόν μέ τάς νεφρικάς μεταμοσχεύσεις. Ή συντονισμένη αύτή προσπάθεια είναι ό μόνος τρόπος έγγυήσεως ότι ένας καλώς έπιλεγμένος θά έξασφαλίση είς κάθε άσθενή μιά βελτιωμένη ποιότητα ζωής.

ΕΞΕΥΡΕΣΙΣ ΔΩΤΟΥ ΝΕΦΡΟΥ

Ένας καλός προγραμματισμός μεταμοσχεύσεως άπαιτεί τήν έπιλογήν τού καταλλήλου νεφρού διά κάθε περίπτωσιν. Είναι σημαντικόν νά γνωρίζωμεν ότι μεταμοσχεύσεις νεφρού άπό ζώντα δώτη, συγγενή τού άσθενούς, έχει μεγαλύτερες πιθανότητες μακοχρονίου έπιτυχίας άπό τάς πτωματικάς μεταμοσχευσεις. Συνεπώς συνιστούμεν είς τούς άσθενείς ύποψηφίους διά μεταμόσχευσιν νεφρού όπως συζητούν μετά τών οίκίων των τήν άνάγκην περιμένει, διά τήν έξευρεσιν τού καταλλήλου νεφρού, μεταξύ μιάς έβδομάδος έως ένός έτους καί καμιά φορά ίσως περισσότερον τού έτους.

Ή μεταμόσχευσις όμως άπό ζώντα δώτη μπορεί νά προγραμματισθή προκαταβολικώς, ούτως ώστε καί ό χρόνος τών αίμοδιαλύσεων νά περιορισθή άφ' ένός, καί άφ' έτέρου ή έπάνοδος τού άσθενούς είς τήν Έλλάδα νά άναμένεται έντός λογικώς μικρού χρονικού διαστήματος. Κάθε συγγενής τού ίδιου τύπου αίματος μετά τού άσθενούς, μπορεί νά θεωρηθή ώς πιθανός δώτης. Εις τήν κατηγοριαν τών πιθανών δωτών περιλαμβάνονται, γονείς, πάπποι, άδελφαί, άδελφοί, έτεροθαλεις άδελφοί καί άδελφαί, άνεψιοί, έξάδελφοι, θείοι καί τέκνα. Ό δώτης δέν πρέπει νά είναι ήλικιας άνω τών 65 ούτε καί κάτω τών 15 έτών. Δύο έξετάσεις αίματος διά τήν διαπίστωσην πιθανού δώτου, μπορούν νά γίνουν είς τήν Έλλάδα καί τά άποτελέσματα νά γνωστοποιηθούν είς ήμάς έντός όλίγων ήμερών. Μετά τήν έπιλογή τού δώτου άπαιτείται έντατική έργασία διά νά διαπιστωθή ότι ή ύγεία τού δώτου δέν πρόκειται νά κλονισθή άπό τήν άφαίρεση τού νεφρού.

ΝΟΣΟΚΟΜΕΙΑΚΗ ΝΟΣΗΛΕΙΑ

Ό άσθενής, έν άναμονή μεταμοσχεύσεως νεφρού ήτε άπό ζώντα δώτη ήτε πτωματικού, θά πρέπει νά είσαχθή είς τό RUSH PRESBYTERIAN - ST. LUKE'S Νοσοκομείον διά έκτεταμένη προκαταρτική έργασία. Άσθενείς ήλικίας μεταξύ 5 καί 65 έτών είναι δυνατόν νά ύποβληθούν είς μεταμόσχευσιν νεφρού. Διά νά άποφευχθούν προβλήματα διαμονής είς τό Σικάγο, άρκετές προετοιμασίες πρέπει νά γίνουν διά κάθε άσθενή ό όποίος έπιθυμεί νά ύποβληθή είς προκαταρτικήν έξέτασιν μεταμοσχεύσεως είς τό Νοσοκομείον μας.

[redacted] καί Έλληνικά. Έάν τούτο είναι άναγκαίον μπορεί νά ρυθμισθή μετά τήν άφιξιν είς Σικάγον.

Προκαταρτικές έγχειρίσεις μπορεί νά κριθούν άπαραίτητες καί ώς έκ τούτου ή παραμονή τού άσθενούς είς τό Νοσοκομείον ίσως νά παραταθή.

Προκαταρτική όδοντιατρική έξέτασις είναι άναγκαία άλλά μπορεί νά γίνη στήν Έλλάδα. Οί άσθενείς θά πρέπει, είς τήν περίπτωσιν αύτήν νά φέρουν μαζί τους καί τάς σχετικάς άκτινογραφίας.

ΚΟΣΤΟΣ ΜΕΤΑΜΟΣΧΕΥΣΕΩΝ

Καθ' όν χρόνον ό άσθενής εύρίσκεται έκτός Νοσοκομείου, αί αίμοδιαλύσεις πρέπει νά γίνωνται είς κέντρον αίμοδιαλύσεων έξωτερικών άσθενών. Αύτά τά κέντρα άπαιτούν πληρωμή προκαταβολικώς, δι' όλους τούς ξένους άσθενείς. Ό άσθενής χρειάζεται τρείς αίμοδιαλύσεις τήν έβδομάδα καί διερμηνέα κατά τήν διάρκειαν τής αίμοδιαλύσεως. Σήμερον τό κόστος κάθε αίμοδιαλύσεως άνέρχεται είς τό ποσόν τών 150 δολλαρίων μή συμπεριλαμβανομένου τού κόστους φαρμάκων, έργαστηριακών έξετάσεων ή μεταγγίσεων. Όταν όλα είναι έτοιμα διά τήν μεταμόσχευσιν ό άσθενής θά πρέπει νά περιμένη έδώ είς τό Σικάγον άπό τρείς μέχρι έξι μήνες διά πτωματικού νεφρόν.

Μετά τήν μεταμόσχευσιν, ό άσθενής πρέπει νά παραμείνη είς τό Σικάγο τρείς μήνες άπό τής έξόδου του έκ τού Νοσοκομείου. Κατά τήν διάρκειαν τού χρόνου τούτου ό άσθενής θά δίδη αίμα δι' έξετάσεις τρείς φορές τήν έβδομάδα μέ σημερινόν κόστος 50 δολλαρίων διά κάθε φορά. Έπί πλέον ό άσθενής θά έξετάζεται είς τά γραφεία μας μιά φορά τήν έβδομάδα.

Mr. GORE. Are you aware of any other solicitation by doctors overseas?

Ms. PEELE. No.

Mr. GORE. Dr. Feduska, let me ask you about this, but prior to doing so, let me say that I think the translation of this document in the record will lead to a question as to whether or not this is the giving of information that induces patients to come in order to get the treatment, or whether it crosses the line into what medical societies would call solicitation. I think it's best to let that pamphlet speak for itself and you can arrive at your own conclusion about it. But let me give you a chance to comment on it.

Dr. FEDUSKA. Well, I can't comment for everyone, certainly, but I can comment for the practice in our own center and I can give you some examples that would shed some light on all of this.

We do not, as I pointed out in my testimony, recruit any patients for transplantation, U.S. citizens or otherwise. However, if you look at the tables relating the various distributions of countries from which these foreign patients have come, clearly there are certain countries that, if you will, are somewhat out of balance.

Now, I think there perhaps are at least two major factors to account for that. One of them is that patients in some countries clearly have different resources available to them to come to a country like ours and receive medical care that is so terribly expensive. Other countries' patients simply don't have that kind of opportunity. I think perhaps this represents the dominant reason why 39 of the cadaver transplant recipients were from Saudi Arabia.

I think another important point, however, is that perhaps one of the biggest proponents of transplantation as an effective therapy is, if you will, a satisfied customer, a patient who has been fortunate to have a successful result. In the past we have had occasion to perform a small number of transplants, as an example, for patients who have been referred to us from Argentina. We have not solicited any patients. We do have a friendship with a surgeon and a nephrologist in that community who have come to our medical center previously to further enhance their background in transplantation and nephrology.

I had the opportunity of being there recently as a visiting professor, and as I was there they asked me if I would speak with two or three other patients who were acquainted with the patients from there who have had successful results and are doing quite well, and now other patients from that same country wish to come to our center to receive a transplant. So I think this is yet another reason why the distribution of countries from which foreign patients come may be somewhat out of kilter if you look at the experience as it is related in tables 1 and 2 in my testimony.

Mr. GORE. Let me ask you about the financial incentive, Dr. Feduska. There are reports that nonimmigrant aliens end up paying more for transplants in some cases than those on the medicare program. There is not a lot of evidence that that has actually produced a skewed result or is responsible for the skewed result. I think what's mainly responsible for it is the way the current system operates to give preference within a specific institution and then within a specific small geographic area.

I think that's why, for example, you have some of these centers that do 50 percent of their transplants on nonimmigrant aliens, 50 percent, 42 percent, 21 percent—and we'll supply these figures for the record. And yet at the same time the figures nationally are so low.

Nevertheless, the question of financial incentives remains one that is a little bit troubling. How do you respond to that? What do you think about it?

Dr. **Feduska**. Well, I welcome the opportunity to respond to that question.

First of all, let me say I can't speak for everyone, but again, speaking for our own program, our practice is to charge foreign patients for professional services rendered in the same amount as we charge patients from this country, most of whom are eligible to have their expenses paid for through the medicare program——

Mr. **Gore**. When you say "we," are you talking about your medical center or your society?

Dr. **Feduska**. I'm speaking of our medical center, our transplant service.

Now, that is our practice, and admittedly, as was alluded to in some of the earlier discussion, foreign patients may very well be in the position of paying the entire amount of the bill while medicare does not reimburse the total amount. Nevertheless, I think that the amount that we propose in our own center is really perfectly acceptable. The professional fee associated with a related or cadaver transplant is approximately $2,000—and this includes all of the necessary preparations prior to the transplant, the performance of the transplant itself, and the management of the followup care, including the management of immunosuppressive therapy through the first 60 days and very often beyond that following the transplant. I think if you were to study these charges or these costs and compare them to other sophisticated kinds of medical and surgical care in this country today, I think you would be very surprised to find that this is, in fact, really quite an excellent bargain.

Mr. **Gore**. I don't think there is any question about that. Indeed, if you compared the charges you just outlined to the charges for the same service at other medical centers, you might find that it was a bargain.

Dr. **Feduska**. But the other point that I would like to make is that from time to time in our own center we have had occasion to provide such transplants for patients who did not have resources, who were not able to pay, and the professional fees were deferred completely. So I'm not sure that the problem is of the magnitude that some of us might think perhaps it is.

Mr. **Gore**. OK. That's fair enough.

One final point. When you gave your percentages on cadaver transplants to nonimmigrant aliens, you included living related donors in the base figure; you took nonimmigrant alien cadaver transplants as a percentage of the total universe of transplants, both cadaver and living related, isn't that correct?

Dr. **Feduska**. Yes, in that center that is so.

Mr. **Gore**. All right. We can clarify that for the record. The effect of a recalculation, excluding the living related donors, would be to put that percentage slightly higher.

Could all of you—would all of you be willing to respond to additional questions for the record? We don't anticipate a large number of them, but in order to flesh out the record without staying here all day asking them all orally? Is that OK?

OK, fine. Thank you very much for your helpfulness here today. We are going to continue these hearings with our third panel now, but I would like to thank this panel particularly because it has an enormous amount of expertise. Thank you very much.

Mr. GORE. Let me call now the final panel of the day, to take Washington, D.C., as a case study: Dr. Jimmy Light, director of transplant surgery at Washington Hospital Center; Dr. George Schreiner, chief of nephrology at Georgetown University Hospital; Dr. Baird Helfrich, director of transplant surgery at Georgetown University Hospital; and Dr. Said Karmi, codirector of transplantation at George Washington University Hospital.

Is Dr. Schreiner here? [No response.] We will wait just 1 second while we try to locate Dr. Schreiner.

Gentlemen, if you would stand and raise your right hand. Do you solemnly swear that the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

[Witnesses answer affirmatively.]

Mr. GORE. Thank you very much. We will, without objection, put all of your prepared statements in the record in full at this point. When Dr. Schreiner returns, I hope he will come on up to the witness table.

We would like to begin with you, Dr. Light. Without objection, as I said, your statements are in the record, and if you care to summarize any portions of your statement, feel free to do so. We look forward to hearing from you and we thank you for being here.

STATEMENTS OF JIMMY LIGHT, M.D., DIRECTOR, ORGAN PROCUREMENT AND TRANSPLANTATION, WASHINGTON HOSPITAL CENTER; G. BAIRD HELFRICH, M.D., DIRECTOR, DIVISION OF TRANSPLANTATION, GEORGETOWN UNIVERSITY HOSPITAL; SAID A. KARMI, PROFESSOR OF SURGERY AND UROLOGY AND CODIRECTOR, GEORGE WASHINGTON UNIVERSITY TRANSPLANT SERVICE; AND GEORGE E. SCHREINER, M.D., PROFESSOR OF MEDICINE AND DIRECTOR, NEPHROLOGY DIVISION, GEORGETOWN UNIVERSITY HOSPITAL

Dr. LIGHT. My name is Jimmy Light. As the new director of organ procurement and transplantation at the Washington Hospital Center, I am pleased to have the opportunity to testify before your committee.

The factors involved in donor kidney allocation and recipient selection are numerous. I will outline for you briefly the system used at the hospital center.

At our hospital, organ allocation is based on the priority system developed by the South-Eastern Organ Procurement Foundation [SEOPF]. Unfortunately, it's actually got an error right at the very top. But essentially it's based on several factors. If we exclude and don't consider for the moment patients who are emergency or urgent patients, because those fall into a special category, and just refer to those who are on the active list waiting, which is what your committee, I think, is addressing primarily, for those on the active lists then, the emphasis is placed on histocompatibility and the need to transplant highly sensitized patients, the ones referred to by Dr Terasaki, that are difficult to transplant because they have reacted strongly to foreign tissue. That term "High PRA," in fact, refers to those highly sensitized patients.

Now, the error is that the very top category, category 1, is 0 HLA (A-B) antigen mismatch, rather than match.

Mr. GORE. Wait just a second. What are you referring to?

Dr. LIGHT. Attachment 1. There is a typo on the first category.

Mr. GORE. All right. We'll make that change for the record and, without objection, that will be included in the record.

Dr. LIGHT. Change it to "mismatch." Then the rest of the system makes sense.

Essentially, it is based on, you know, as I mentioned, the commonality in tissue typing and the need to transplant patients who are highly sensitized.

In recent months HLA matching has been less strongly emphasized than DR matching, because it is believed that DR matching means an improved outcome for the recipients. Thus, all recipients at the Hospital Center have been listed on the computer for 2 HLA and 1 or 2 DR matches, regardless of country of origin.

From 1981 to 1983 the Hospital Center performed 89 cadaver kidney transplants, with 71 percent of the kidneys made available from the organ-sharing networks, through the computer selection process. With local donors, those who come within our own area, the same principles have been followed. Kidneys are matched with the appropriate transplant center based on the computer printout and the priority system. In the years 1981 to 1983, we procured 130 kidneys, of which 75 percent were sent to other transplant centers.

When we analyze the distribution between the nonresident aliens and our medicare beneficiaries, we find that they get equal percentages of both locally obtained and imported kidneys.

In the distribution of organs that cannot be used at one's own center, the degree of matching between donor and recipient plays a substantial role in determining how organs are shared. Thus, the better the match for the recipient, the greater the possibility that another center will accept the organ for its patient. This is especially true for highly sensitized patients where a better match means there is less probability for a positive cross-match, which precludes the possibility of transplantation for that recipient and could possibly lead to discarding the kidney, primarily because of excessive preservation time.

In the years mentioned we have used or placed 93 percent of our locally procured kidneys and used all but two imported kidneys. With the imported kidneys, in seven cases kidneys were sent on to other centers, and in two cases, an alternative recipient was chosen other than the one for whom the kidney was originally sent because the two original intended recipients had positive crossmatches.

In deciding whether to accept a kidney for a patient, there are several factors to consider, and you have heard those previously today and I'll not labor through those at the moment.

These clinical factors are unique to each case and it's difficult to form any specific rules about this part of the process.

The issue of who has priority in receiving kidneys is clearly before the committee and addresses the citizens versus nonresident aliens. Washington, D.C., is an international city, with many foreign nationals and nonresident aliens receiving health care here, and so forth.

Of the 89 transplants done at the Hospital Center between 1981 and 1983, 27 were for nonmedicare recipients. Those, I think, are listed as attachment 2 and denotes them by the years. The center has no formal agreements with other nations regarding transplant patients. They are referred to the hospital by other physicians or sometimes by previous patients. Maintenance dialysis services are provided by a variety of nephrologists practicing at the center while the patients are being evaluated or prepared for transplantation, or waiting for a donor organ.

It has been suggested that when nonresident aliens receive kidneys they are buying their way to the top of the transplant list and displacing Americans. To the best of my knowledge, the Washington Hospital Center does not have differential rates according to nationality, race, creed or color. In six randomly selected cases, no significant differences in cost were apparent between the alien group and the resident group.

At present, the Hospital Center does not have an institutional policy regarding organ allocation. One of my first acts there as director of the services was to recommend a policy for approval of our board of trustees. The board has indicated that the committee of bioethics be involved in the formulation of that policy.

In my opinion, as a practitioner in transplantation, this kind of policy should have certain elements. First, it should have a clear statement that we will not become involved in the brokering of organs for transplantation. Second, citizens of the United States should be given priority consideration when cadaver organs are available. Third, so that donated organs not be wasted, nonresident aliens would be considered when first priority recipients are incompatible. And fourth, kidneys or other organs not used in the continental United States for these above categories be placed internationally.

Finally, administrative responsibility for organ allocation should be clearly defined as resting with the director of such services who should exercise this responsibility in coordination with the priorities established by local, regional, and national organ-sharing networks.

It has been suggested that a system of donor and recipient matching be developed where resident status is specifically taken into account as part of the matching process. If computers were programed to print sequential lists for medicare recipients and nonmedicare recipients, then the medicare list could be given the first priority after which nonmedicare recipients could be considered, much as we distribute organs between the continental United States and other nations now. All programs would obviously need to adhere to this kind of policy for it to have any effectiveness.

I think double standards such as this are troublesome and seem to violate, at least in spirit, our country's code of equal access. For example, I am personally not anxious to return to the 1960's and the committee approach to determining who would receive chronic dialysis. Those distasteful decisions that were sometimes necessary influenced the Nation's determination to establish a Federal renal program so that choices could be made solely on clinical criterion.

Transplants for nonmedicare recipients have certain similarities to the early days of kidney dialysis. Perhaps the solution lies with increasing donor resources just as was done with the availability of dialysis treatments, rather than restricting recipient access based on national origin. The other alternative is to assist other countries in developing the technology necessary to establish appropriate resources within the countries needing the service.

I will be happy to answer any questions.

[The prepared statement of Dr. Light follows:]

Testimony of Dr. Jimmy Light
Washington Hospital Center

My name is Dr. Jimmy Light. As the new director of organ procurement and transplantation at the Washington Hospital Center, I am pleased to have the opportunity to testify before your committee. Last year, 5,200 kidney transplant operations were performed in this country. But at this moment, more than 8,000 people across the United States are awaiting suitable kidneys. The factors involved in locating a good match between a donor kidney and an organ recipient are numerous and I'd like to outline for you the system we use at the Washington Hospital Center.

Organ allocation at our hospital is based on the formal priority system developed by the Southeastern Organ Procurement Foundation (SEOPF). (see attachment #1) This system gives priority to those listed as emergency cases, meaning death is imminent; then to those listed as urgent; and finally, to those on the "active" list, the majority of patients awaiting kidneys.

Emphasis is placed on histocompatibility, that is tissue typing, and the need to transplant highly sensitized patients, those who are difficult to transplant because they react strongly to foreign tissue. The term "High PRA," which is at the top of each match category, refers to these highly sensitized patients.

In recent months, *HLA matching has been less strongly emphasized than **DR matching because it is believed that DR matching means an improved outcome for the recipients. Thus, recipients have been listed on the computer for 2 HLA and 1 or 2 DR matches.

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* HLA - refers to human leukocyte antigens, or the markers on human cells that allow them to be identified by tissue-typing techniques.

** DR - a subset of the HLA system that refers to a certain group of markers on human cells. DR matching has recently been shown to increase transplantation success.

From 1981 - 1983, the Washington Hospital Center performed 89 cadaver kidney transplants, with 71 percent of the kidneys made available through computer selection. With local donors, those who come from within the catchment area of the transplant center, the same principles have been followed: kidneys are matched with the appropriate transplant center based on the computer printout and the priority system. In the years 1981 - 1983, the Center procured 130 kidneys, of which 75 percent were sent to other transplant centers, demonstrating adherance to the formal computerized priority system.

In the distribution of organs that cannot be used at one's own center, the degree of matching between donor and recipient plays a substantial role in determining how organs are shared. The better the match for the recipient, the greater the possibility that another center will accept the organ for its patient. For highly sensitized patients, a better match means there is less chance for a positive *cross-match, which would preclude any possibility of transplantation for that recipient and possibly lead to discarding the kidney.

We used or placed 93 percent of locally procured kidneys and used all but 2 imported kidneys. In 7 cases, kidneys were sent to other centers and in 2 cases, an alternative recipient was chosen other than the one for whom the kidney was originally sent.

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* cross-match - pre-operative test that determines reactivity of potential recipient to the donor kidney. A positive result means the patient reacted against the kidney; a negative result means there was no detectable reaction.

In deciding whether to accept a kidney for a patient, there are several factors to consider other than histocompatibility:

- the recipient's past medical history and present medical condition;
- previous transplant;
- waiting period;
- the "quality" and length of preservation of the organ;
- procurement surgery;
- kidney anatomy; and
- status of the transplant donor.

These "clinical factors" are unique to each case and it's difficult to form any specific rules about this part of the process.

Another aspect of transplantation is the aspect you are interested in specifically. That is the issue of who has priority in receiving kidneys: United States citizens or non-resident aliens. Because Washington, D.C., is an international city, many foreign nationals and non-resident aliens receive health care here.

Of the 89 transplants performed at the Washington Hospital Center between 1981 and 1983, 27 were for non-Medicare recipients. The Center has no formal agreements with other nations regarding transplant patients. These patients are referred to the hospital by other physicians or sometimes by previous patients. Maintenance dialysis services are provided by a variety of nephrologists practicing at the Center while patients are being evaluated or prepared for transplantation, and while waiting for a donor organ.

It has been suggested that when non-resident aliens receive kidneys, they are "buying their way to the top of the transplant list" and displacing Americans. To the best of my knowledge, the Washington Hospital Center does not charge differential rates according to nationality, race, creed or color. In six randomly selected cases no significant difference in cost was apparent.

In addition, the committee has requested that I address the question of whether any foreign nationals have been placed out of turn at the head of any transplant priority list used by the Washington Hospital Center. I am not specifically aware of any such occurrence, because I was not involved in patient care at the Center until recently.

At present, the Washington Hospital Center does not have an institutional policy regarding organ allocation. As one of my first acts as Director of Transplantation Services at the Center, I am recommending a policy for the approval of our Board of Trustees. The Board has indicated that the institution's committee of bioethics be involved in the formulations of such a policy.

It is my opinion, as a practitioner in this specialty, that such a policy should have certain elements. First, this should include a clear statement that the institution will not become involved in the brokering of organs for transplantation. Secondly, that citizens of the United States be given priority consideration when cadaver organs are available. Thirdly, so that donated organs not be wasted, non-Medicare recipients will be considered when first priority recipients are incompatible.

Finally, administrative responsibility for organ allocation should be clearly defined as resting with the director of such services, who should exercise this responsibility in coordination with the priorities established by local, regional and national organ sharing networks.

It has been suggested that a system of donor and recipient matching be developed where resident status is specifically taken into account as part of the matching process. If computers were programmed to print sequential lists for Medicare recipients and non-Medicare recipients, then the Medicare recipient list would be given first priority, after which the non-Medicare recipients would be considered. All programs would need to adhere to this policy for it to be effective.

Double standards as proposed above are troublesome and seem to violate, at least, in spirit our country's code of equal access. For example, I personally am not anxious to return to the 1960s and the "committee approach" to determining who would receive chronic dialysis. The distasteful decisions that were sometimes necessary influenced the nation's determination to establish a federal renal program. In this model, access choices were made solely on clinical criteria.

Transplants for non-Medicare recipients have certain similarities to the early days of kidney dialysis. Perhaps the solution lies with increasing donor resources just as was done with the availability of dialysis treatments, rather than restricting recipient access based on national origin. The other alternative is to assist other countries in developing the technology necessary to establish appropriate resources within the countries needing the service.

I will be happy to answer any further questions the committee may have.

CURRICULUM VITAE

Jimmy A. Light

PERSONAL DATA:

Birth: November 3, 1938, Liberty Center, Ohio
Marriage: Sharon, February 21, 1959
Children: Amy 1961, Libby 1962, Timothy 1967

EDUCATION AND TRAINING:

B.S., 1960 - Bowling Green State University
M.D., 1964 - University of Michigan Medical School
Internship & Residency (General Surgery) - Walter Reed Army Medical Center, 1964-69
Research Fellowship Training Program, Walter Reed Army Institute of Research, 1970-71
NIH FAES Post-graduate Programs in Immunology, 1970-72

MILITARY ASSIGNMENTS:

ROTC, 1956-60
Army Senior Medical Student Program, 1963-64
Internship & Residency (General Surgery), Walter Reed Army Medical Center, 1964-69
Viet Nam, 1969-70, Chief of Surgery & Chief of Professional Services, 71st Evacuation Hospital and Command Surgeon - 20th Engineer Brigade
Research Fellowship Training Program, Walter Reed Army Institute of Research, 1970-71
Staff Surgeon, Organ Transplantation Service, Walter Reed Army Medical Center, 1971-73
Assistant Chief, Organ Transplantation Service, Walter Reed Army Medical Center, 1973-77
Chief, Combined Army-Navy Transplantation Service, July 1977

AWARDS:

Rollo E. McDotter Award	1961
Dean's List (Medical School)	1961-64
Special Studies Research Group	1961-64
Roche Award for Basic Science Studies	1962
AOA President	1963-64
Phi Kappa Phi Honor Society	1964
Salutatorian Medical School Class	1964
Outstanding Young Men of America	1969
Bronze Star	1970
Dr. Peter F. Salisbury Outstanding Scientific Exhibit Award	1975
Distinguished Alumnus Award of Bowling Green State University	1977
"A" Professional Designator Award	1980
National Kidney Foundation Distinguished Service Award	1981

HONORARY SOCIETIES:	Alpha Omega Alpha (President)	1963-64
	Phi Kappa Phi	1964
DIPLOMATE:	American Board of Surgery	1970
PROFESSIONAL SOCIETIES:	American Medical Association	
	Medical Society of the District of Columbia	
	Fellow, American College of Surgeons	
	Transplantation Society	
	American Society of Transplant Surgeons	
	Association for Academic Surgery	
	American Society for Artificial Internal Organs	
	American Society of Nephrology	
	International Society of Nephrology	
	Association of Military Surgeons of the United States	
	Washington Area Transplant Society	
	Society of University Surgeons	
BOARDS, COMMITTEES AND APPOINTMENTS:	Kidney Foundation of the National Capital Area	
	Board of Directors	1978-
	Chairman, Public Education Committee	1981-
	Washington Area Transplant Society	
	Board of Directors	1975-
	Vice President	1975-1978
	President	1978-79
	South Eastern Organ Procurement Foundation	
	Secretary	1972-74
	Board of Directors	1972-
	Chairman, Transportation Committee	1977-79
	Chairman, Data Acquisition Committee	1979-
	Scientific Projects Publication Committee	1981-
	Subcommittee on High PRA Patients	1981-
	Subcommittee on Donor Specific Transfusion	1981-
	Renal Physicians Association	
	Board of Directors	1975-78
	Organizer, Annual WATS Symposium	1977, 1978
	Associate Professor of Surgery, Chief, Division of Transplantation, Uniformed Services University of the Health Sciences	1978-79
	Professor of Surgery, Chief, Division of Transplantation, Uniformed Services University of the Health Sciences	1979-

BOARDS, COMMITTEES AND APPOINTMENTS:	Organizer, Organ Donation; A Team Approach, Walter Reed Army Medical Center	1979
	Credentials Committee, Department of Surgery, Walter Reed Army Medical Center	1981
	Member, D.C. Medical Society Ad Hoc Committee on Brain Death Legislation for the District of Columbia	1980
	Member, Admissions Committee, Uniformed Services University of the Health Sciences	1980-81
	Member, Kidney Dispatch Center Study Committee, South Eastern Organ Procurement Foundation	1981
	Faculty, Course in Continuing Education, Pathology of Medical Renal Diseases, Armed Forces Institute of Pathology	1981
	Faculty, 2nd Annual Tennessee Renal Disease Symposium, National Kidney Foundation of West Tennessee, Inc, Memphis	1981
	Member, Blood Products Advisory Committee, Bureau of Biologics	1981
	Consultant in Renal Transplant to Surgeon General	1982
	Alumni Board of Trustees, Bowling Green State University, Bowling Green, Ohio	1982
	Member, Transplantation Biology and Immunology Subcommittee, National Institute of Allergy and Infectious Diseases, National Institutes of Health	1982
	Member, Membership Committee, American Society of Transplant Surgeons	1982
	Member, Grants Review Committee, Kidney Foundation of National Capital Area	1982
	Vice President, Kidney Foundation of National Capital Area	1982
	Member, Medical Advisory Committee, North American Transplant Coordinators Organization	1983

Light
Washington Hospital Center
Attachment #1

PRIORITIZATION OF ADULT KIDNEY PLACEMENT

1) 0 HLA (A-B) Antigen ~~Match~~ MISMATCH
   - a) High PRA with negative preliminary crossmatch
   - b) Medical emergency
   - c) High PRA with low PRA backup
   - d) High PRA
   - e) Low PRA

2) 2 HLA DR Match less than 30% PRA
   - a) Medical emergency
   - b) High PRA with low PRA backup
   - c) High PRA
   - d) Low PRA

3) 3 HLA Antigen Match
   - a) High PRA with negative preliminary crossmatch
   - b) Medical emergency
   - c) High PRA with low PRA backup
   - d) High PRA
   - e) Low PRA

4) 2,3, or 4 HLA Mismatch
   - a) High PRA with negative preliminary crossmatch
   - b) Medical emergency
   - c) Share according to proximity and ease of transport

The above prioritization should be used in all cases with kidneys under 18 hours on ice preservation and 24 hours on machine preservation.

Light
Washington Hospital Center
Attachment #2

TOTAL TRANSPLANTS PERFORMED

YEAR	TOTAL TRANSPLANTS	MEDICARE	NON-MEDICARE
1981	21	20	1
1982	33	22	11
1983	35	20	15
TOTAL	89	62	36

Mr. GORE. Thank you very much. We will hold questions until the other panelists have completed their statements.

I guess we will hear next from Dr. G. Baird Helfrich, director of transplant surgery at Georgetown University Hospital. Dr. Helfrich, welcome.

Dr. HELFRICH. Thank you, Mr. Gore.

In response to your request for testimony, I would like to begin by stating that the Investigations and Oversight Subcomittee review of acquisition of human organs for transplantation is appropriate and necessary. I concur with your inquiry, especially in reference to the potential harm that may come to the end-stage renal disease program if nonresident aliens are being given unwarranted priority over medicare recipients or U.S. citizens because of financial or other nonmedically indicated reasons for organ transplant allocation.

In response to your specific questions, I will review in testimony these responses that are included in my written statement.

What priority systems do we use at Georgetown? The response is that Georgetown prioritizes with emphasis on histocompatibility, clinical factors, patient's serum sensitivity, preservation time, and proximity and ease of transport of the organs.

As it may be clear to some people but not to others, the longer that the organs are preserved, the greater the chances of nonfunction, and there is a specific time limit at which point in time the organ's probability of function is low.

The kidney patient prioritization list that we use is in this testimony. Is fairly complex, but it is applied to all organs that are procured by Georgetown. We do not keep one organ and send one organ to another area of the country, for instance. In addition, the sharing criteria are those of the organ sharing organization that we belong to, which is SEOPF.

Do we have a stated policy on priority according to nonresident aliens? Yes. Our stated policy has been in effect in written form since 1981, and since that time we have utilized organs which would not otherwise have been placed in U.S. citizens for the foreign patients. In other words, all U.S. citizens are offered the kidney, and if the kidney would otherwise have been discarded, it is then accepted for a foreign national. All foreign nationals transplanted at Georgetown are informed of this policy prior to acceptance as a patient. They are also reviewed by the Department of Nephrology for medical suitability in a frame of reference very similar to Dr. Feduska's earlier statement.

Kidney transplants performed, the data. Of 129 transplants performed in the last 3 years, 32 were from foreign nationals at a rate of 25 percent.

How do nonresident aliens come to our institution? Referrals for transplantation come from patients, physicians, and foreign governments. Our referrals are received at the transplant office from the division of nephrology, from private referrals and from Georgetown affiliated dialysis units. Patient referrals are also received. It has been our policy that foreign national patients be reviewed for suitability for transplantation by the division of nephrology prior to acceptance for transplantation and no agreement with foreign governments exists with the transplant division or the department of surgery.

If you or your institution are in agreement with foreign governments. The transplant division has no agreement with foreign governments.

Do you or your institution charge differential rates, and the answer is no. Our collection rates, which are important—the collection rates have been referred to in the press for foreign nationals—we do not collect a higher percentage on bills than for American citizens.

Are you aware of foreign nationals who have been placed out of turn on any transplant list, and the answer is no, that no foreign national at Georgetown has received a kidney which would have not otherwise been discarded, and I am aware of foreign nationals in the United States who do receive kidneys on medical indications rather than prioritization as to national origin.

Do you believe there should be a uniform established policy on transplantation? Personally, I believe that a foreign national is a patient and should be treated as a patient. Medical considerations should dictate sharing of transplantable tissues. When a foreign national, such as the boxer, Mr. Kim, dies in this country, his organs are not prioritized toward non-U.S. citizens. I think the distinction toward care based on nationality is a mistaken concept and that the issue of a medical decision should not be influenced by geopolitical considerations. I would much rather see foreign nations support the U.S. organ recovery program, and a wide acceptance of foreign national patients, than I would a restrictive policy which discriminates on the basis of national origin. I would strongly encourage this committee to consider the foreign national as a patient rather than a disenfranchised individual merely because his government does not support organ recovery in the United States, or he is not a U.S. citizen. In short, the best patient to receive a kidney should be the patient who is medically indicated to be the best recipient.

The most important ethical considerations relating to this issue of allocation of scarce medical resources are that the resources should be allocated on medical indications. Introduction of nonmedical criteria such as nation of origin or personal wealth for allocation of such resources are contrary to most codes of medical ethics. Reference AMA code.

How do other countries handle questions? I have had some experience with foreign countries and have been asked to do transplantation in foreign countries. And to my knowledge, no foreign country, until the testimony today concerning those of the English donors, no foreign country to my knowledge has a national policy on allocation of these organs.

On what basis are organs sent out of the United States? We have prioritized the sharing of kidneys for first U.S. citizens and then non-U.S. citizens residing in the country, and then finally, out of the country. We sent one kidney—in 1981, 1982, 1983—to Turkey in 1983.

In summary, I am pleased to be able to offer my contributions to your investigation of transplantation of nonmedicare recipients. Clarification of the medical integrity of individuals involved in transplantation of foreign nationals is needed and should be pursued by the committee. While it may not be the most popular position, it is my strong personal belief that allocation of such organs on any criteria other than medical indications will result in very serious ethical implications. For this reason, I would strongly urge the subcommittee to pursue the increased recovery of transplantable organs rather than a limitation of current availability to first U.S. citizens as recipients on a priority basis, then to nonresident aliens.

[The prepared statement of Dr. Helfrich follows:]

STATEMENT OF G. BAIRD HELFRICH, M.D.
Director, Division of Transplantation
Georgetown University Hospital:

FOR: Representative Albert Gore, Jr.
Chairman, Subcommittee on Investigations and Oversights
U.S. House of Representatives

In response to your request for testimony, I would like to begin by stating that the Investigations and Oversights Subcommittee review of acquisition and distribution of human organs for transplantation is appropriate and needed. I concur with your inquiry, especially with reference to the potential harm that may come to the ESRD Program if non-resident aliens are being given unwarranted priority over Medicare recipients or U.S. citizens because of financial, or other non-medically indicated reasons for organ transplant allocation.

My testimony as follows is in response to your letter of 10/19/83 requesting answers to specific questions:

1. What priority systems do you/your organization use for the allocation of human organs (kidneys)? How much emphasis do you place on histocompatibility, clinical factors, and patients sensitivity?

   Georgetown prioritizes with emphasis on histocompatibility, clinical factors, patient's serum sensitivity, preservation time and proximity and ease of transport of the organs.

Prioritization of Kidney Placement - Georgetown University Hospital

1) 0 Mismatch Human Leukocyte Antigen (HLA) A-B Antigen
   - a. High Percent Reactive Antibody (PRA) with negative preliminary crossmatch
   - b. Medical Emergency
   - c. High PRA with low PRA backup patient
   - d. High PRA
   - e. Low PRA

2) 2 HLA D-Region Related (DR) Match $\leq$ 30% PRA
   - a. Medical Emergency
   - b. High PRA with low PRA backup patient
   - c. High PRA
   - d. Low PRA

3) 3 HLA (A-B) Antigen Match
   - a. High PRA with negative preliminary crossmatch
   - b. Medical Emergency
   - c. High PRA with low PRA Backup patient
   - d. High PRA
   - e. Low PRA

4) 2, 3, or 4 HLA (A-B) Mismatch

a. High PRA with negative preliminary crossmatch
b. Medical Emergency
c. Share according to proximity of ease of transport

The above prioritization would be used in all cases with kidneys under 18 hours old on ice preservation and 24 hours old on machine preservation.

5) Notify Kidney Center for assistance in matching as early as possible for difficult-to-place kidney donors.

2. Do you have a stated policy on the priority accorded to non-resident aliens?

Our stated policy has been in effect since 1981. To our knowledge, no non-resident alien has received a transplant at Georgetown which kidney would not have otherwise been discarded since the program was initiated in 1964.

3. How many kidney transplants were performed in your institution in 1981, 82, and 83? How many of these were on non-resident aliens?

1981/39 (12 Living-Related, 27 Cadaver),
1982/45 (13 Living-Related, 34 Cadaver), &
1983/45 (14 Living-Related, 33 cadaver), to date.

Transplants to foreign nationals:

1981 - 3 transplants
1982 - 14 transplants from seven different countries.
1983 - 15 transplants from six different countries.

4. How do non-resident aliens come to your institution? Referral? Agreements with foreign government?:

Referrals for transplantation come from patients, physicians, and foreign governments. Our referrals are received at the Transplant Office from the Division of Nephrology, from private referrals from Georgetown affiliated dialysis units, and from patient referrals. It has been our policy that foreign national patients be reviewed for suitability for transplantation by the Division of Nephrology prior to acceptance for renal transplanation and no agreement with foreign governments exists with the Transplant Division and the Department of Surgery.

5. If you or your institution are in agreement with the Foreign Governments. Which governments? What are the nature of these agreements:

The Division of Transplantation has no agreement with foreign governments.

6. Do you or your institution charge differential rates to achieve additional payments from or/on behalf of non-residents, aliens or other non-Medicare patients for organ acquisition, hospitalization, or transplant surgery.

No, and our collection rates for foreign nationals are not higher than for U.S. citizens in either physicians' charges, hospital billings, or laboratory services.

7. Are you aware of any foreign nationals who have been placed out of turn on any transplant list?

No foreign national at Georgetown has received a kidney which would not have otherwise been discarded. I am aware of foreign nationals who have received kidneys in the United States based on medical indications for transplantation and tissue matching as opposed to using national origin as indication for priority for transplantation. I am not aware of any foreign national who has been placed at the head of any transplant priority list because of more favorable financial considerations.

8. Do you believe there should be a uniform established policy on transplantation of non-resident aliens? If so, what mechanism system would you recommend?

I believe that a foreign national is a patient and should be treated as a patient. Medical considerations should dictate sharing of any transplantable tissue. When a foreign national dies in the U.S., such as the boxer, Mr. Kim, his organs are not prioritized toward foreign national recipients. I think that the distinction of care based on nationality is a mistaken concept and that the issue of a medical decision should not be interefered with by geopolitical considerations. I would much rather see foreign nations support the U. S. organ recovery program, and a wide acceptance of foreign national patients than I would a restrictive policy which discriminates on the basis of of national origin. I would strongly encourage the Committee to consider the foreign national as a patient rather than a disenfranchised individual because his government does not support organ recovery in the U.S. In short, the best patient to receive a kidney should be the prioritized recipient on strictly medical criteria regardless of his nationality.

9. What ethical considerations are important to consider on the issue of allocation of what may be scarce medical resources?

The most important ethical considerations relating to the issue of allocation of scarce medical resources are that the resources are to be allocated on medical indications. Introduction of non-medical criteria such as nation of origin or personal wealth for allocating such resources are contrary to most codes of medical ethics. (Reference AMA Code of Medical Ethics).

10. How do other countries handle the questions of allocations of organs for transplantation? Transplantation of Non-Resident nationals:

    My experience with foreign countries relates to individual physicians from different individual programs in those countries. I am not aware of any nation having developed a national policy for allocation of organs for transplantation. To my knowledge, the allocation of organs in foreign countries is based on medical need and the usual prioritization of recipients along transplantation protocols.

11. On what basis are organs (kidneys) sent out of the U.S.? How many such organs are sent out of the U.S. by your organization? To what countries?:

    Our organ sharing network is responsible for prioritizing and sharing kidneys which are contributed by the Georgetown Organ Recovery Program. We utilize the SEOPF and other computers to place such organs. The organ goes to the best recipient based on medical criteria. The Georgetown Organ Recovery Program has placed kidneys in the following countries:

    1981 - None
    1982 - None
    1983 - One sent to Turkey

In summary, I am very pleased to be able to offer my contributions to your investigation of transplantation of non-Medicare recipients. Clarification of the medical integrity of individuals involved in transplantation of foreign nationals is needed and should also be pursued by the Committee. While it may not be the most popular position, it is my strong personal belief that allocation of such organs on any criteria other than medical indications will result in very serious ethical implications as we have seen in the historic treatment of White and Black patients in our own country. For this reason, I would strongly urge the Sub-Committee to pursue the increased recovery of transplantable organs rather than limiting the current availability of organs to first U.S. citizens as recipients on a priority basis then to non-resident aliens.

Mr. **Gore**. Thank you very much. We'll come back with questions.

I would like to call now on Dr. Said Karmi, codirector for transplantation, at George Washington University Hospital. We appreciate your presence here today, Dr. Karmi, and please proceed.

Dr. **Karmi**. Thank you very much, Mr. Gore.

The George Washington University Medical Center's policy on organ donation does not discriminate on the basis of sex, race, religion, or national origin. Patients suffering from many diseases are referred to the university hospital from all around the world. We feel that we cannot deny any patient any method of treatment, including organ transplantation. It is against all medical ethics, medical professionalism, to deny treatment of any kind to any patient.

In the Washington metropolitan area there are five medical centers performing transplants. Because Washington is an international city, many patients are referred to the various centers from overseas. Some come independently seeking a transplant, and some come at their government's expense.

Some patients prefer to come to Washington because their embassies are located here, but the number that we have is not that excessive.

Once the patient is approved as an acceptable transplant candidate from a medical point of view, that patient is put on a transplant list. This computerized list includes all of the possible recipients in the Washington area. Enclosed in my testimony you will find the organ procurement hospital designation in the Washington area.

There are five medical centers, as I said, performing the transplants, and these medical centers have affiliated hospitals in their domain. When a donor is available, the team from the medical center evaluates the potential donor, and if there's a good match for that patient at a particular center, then the kidney is given there. Otherwise, other centers in the region are contacted, then SEOPF, then the rest of the United States.

We have had two incidents where kidneys were sent outside the United States from George Washington Hospital; one was sent to Rome and one was sent to Singapore.

At George Washington University Medical Center at no time is a foreign national given priority on the transplantation list. On some occasions certain patients are put on what is called an emergency or an urgent list; none of these were foreign nationals. The indication was purely medical.

In 1980 there were 20 transplants performed—4 of these patients were foreign nationals. One recipient was an Indian—he happened to be the ex-Ambassador. One was from Argentina and one from Turkey, and one from Syria who received a living-related kidney from his mother.

In 1981 there were 22 transplants performed, 3 on foreign nationals, 1 from Argentina, 1 from Sudan, and 1 from Turkey. In 1982, 18 transplants were performed, 4 on foreign nationals, 2 were from Saudi Arabia, 1 from Iraq, and 1 from Turkey. So far in 1983 there was only one foreign national receiving it.

At the present time George Washington receives patients from the Embassy of Qatar, the Turkish Embassy, and the Military Attache's Office of the Saudi Embassy. There are no signed agreements with these governments, but the embassies do choose certain universities to send their patients to and generally send patients to more than one medical center.

Much has been said about giving priority to foreign patients because of financial advantages. This is untrue as far as we are concerned. Potential patients are given a statement which details estimated expenses, which is appendix IV. The patients must pay the estimate of the total expenses in advance, or they must be insured through the medicare program or have coverage through a verifiable third party insurance carrier. This financial policy relative to transplant patients is the same policy for all elective surgical admissions at the George Washington University Center. Other countries, such as Great Britain, do have a policy which includes giving kidneys only to British citizens and sometimes citizens from the Commonwealth. The medical profession in the United States, however, is completely different than that of Great Britain and it is the best in the world. It has its own governing body and can take care of its own regulations and policies.

The decision of who gets the kidney and by whom is a very sensitive subject these days. There are many variables and considerations with each kidney transplant which must be specifically analyzed and applied to each patient. The medical expertise and experience needed in making these decisions cannot be replaced by any other person or body than the medical people involved. When a surgeon decides to put a kidney into his patient, it is his moral, ethical, and medical responsibility to take care of that patient. He spends his nights performing the surgery and the months after taking care of the patient. I feel that no one else should make the decision about which kidney goes to which patient, other than the one who is performing the surgery and is ultimately responsible for the life of the patient and the outcome of the transplantation.

Thank you very much for your time.

[The prepared statement of Dr. Karmi follows:]

THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Department of Urology
(202) 676-4002

The H.B. Burns Memorial Building / 2150 Pennsylvania Avenue N.W. / Washington, D.C. 20037

TESTIMONY TO BE PRESENTED BEFORE

THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

CONGRESSIONAL COMMITTEE ON SCIENCE AND TECHNOLOGY

Dr. Said A. Karmi

November 7, 1983

BIOGRAPHICAL SKETCH

Said A. Karmi, M.D.

Said A. Karmi was born in Jordan in 1937 and completed his undergraduate education at the American University in Beirut, Lebanon. Dr. Karmi received his M.D. degree in 1964 at the American University in Beirut. He then completed five years of residency in surgery at the American University Hospital in Beirut before beginning his residency in urology at Georgetown University. Dr. Karmi spent three years as a resident in urology at Georgetown University Hospital before returning to Jordan to serve as the Chief of Urology at the Army Base Hospital in Amman. Following his tenure in the Jordanian army, Dr. Karmi became a U.S. citizen and spent one year as a Clinical Fellow in Urology at Georgetown University Hospital. He then became an Assistant Professor of Surgery and Urology at the University of Maryland Hospital. In 1980 Dr. Karmi came to the George Washington University Medical Center where he now serves as a tenured Full Professor of Surgery and Urology and Co-Director of the George Washington University Transplant Service.

Dr. Karmi is certified by the American Board of Surgery and the American Board of Urology. He is an active member of numerous surgical and urological associations and served as Vice President for the Washington Area Transplant Society. He has published widely on subjects ranging from renal transplantation to renal tumors. Dr. Karmi is currently responsible for training residents in urology and surgical residents on rotation with the transplant service and teaches two courses for third and fourth year medical students at George Washington University Medical Center.

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TESTIMONY TO BE PRESENTED BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE CONGRESSIONAL COMMITTEE ON SCIENCE AND TECHNOLOGY
NOVEMBER 7, 1983

The George Washington University Medical Center's Renal Transplantation Program is dedicated to providing the maximum required health care services for patients suffering from end stage renal disease. Since the brain death laws came into effect in most of the states the number of kidney transplants has increased considerably. Organ donations require intensive public education and generate numerous discussions regarding religious, ethical and moral considerations. It is because of these donations that life can be offered to people suffering from devastating diseases. The George Washington University Medical Center's policy on organ donation does not discriminate on the basis of sex, race, religion or national origin. (Appendix I) Patients suffering from many diseases are referred to the University Hospital from all around the world. End stage renal disease is treated in two ways. Either the patient remains on dialysis or receives a kidney from a cadaver or a living related donor. We at George Washington University Medical Center feel that we cannot deny any patient any method of treatment including organ transplantation. It is against all medical ethics and medical professionalism to deny treatment of any kind to any patient.

In the Washington Metropolitan area there are five medical centers performing transplants. Because Washington is an international city, many patients are referred to the various centers from overseas. Some come independently seeking a transplant and some come at their government's expense.

Some patients prefer to come to Washington because their embassies are located here but the number of patients who do so is not excessive. They are distributed among the various medical centers in the Washington metropolitan area. When a patient comes to the Renal Division of the George Washington University Medical Center, that patient is evaluated regarding the possibility of maintenance on dialysis or the necessity for kidney transplantation. Once the patient is approved as an acceptable transplant candidate from a medical point of view that patient is put on a transplant list (Appendix II). This computerized list includes all of the possible recipients in the Washington area. Enclosed you will also find the organ procurement hospital designation in the Washington area (Appendix III). There are five medical centers, including George Washington University, Washington Hospital Center, Georgetown University, Howard University and Walter Reed. These medical centers have affiliated hospitals in their domain. When a donor is available the team from the medical center evaluates the potential donor. If there is a good match for that patient at our center then the patient receives the kidney. If, however, there are no patients available for that particular kidney, it is offered to other centers in the Washington area depending on the tissue typing and matching. If there is no good match in the Washington Metropolitan area, other areas in the U.S. are approached through other computer lists. We have had two incidences where kidneys were sent outside the U.S. from George Washington Hospital; one was sent to Rome and one to Singapore.

At George Washington University Medical Center at no time is a foreign national given priority on the transplantation list. On some occasions certain patients are put on what is called an "emergency" or an "urgent" list. The indication for such a placement is that the patient is very ill, on dialysis, whose only chance of survival is kidney transplantation. At George Washington University in 1980 there were 20 transplants performed. Four of these patients were foreign nationals. One recipient was the Indian Ambassador to the U.S., one was from Argentina, one from Turkey and one from Syria who received a living-related kidney from his mother. In 1981 there were 22 transplants performed, three on foreign nationals. One recipient was from Argentina, one from the Sudan and one from Turkey. In 1982, 18 transplants were performed, four on foreign nationals. Two were from Saudi Arabia, one from Iraq and one from Turkey. So far in 1983, 16 transplants have been done with only one recipient a foreign national. At the present time George Washington University receives patients from the Embassy of Qatar, the Turkish Embassy and the Military Attache's Office of the Saudi Embassy. There are no signed agreements with these governments, but the embassies do choose certain universities to send their patients to and generally send patients to more than one medical center.

Much has been said about giving priority to foreign patients because of financial advantages. This is completely untrue as far as George Washington is concerned. Potential patients are given a statement which details estimated expenses (Appendix IV). The patients must pay the estimate of the total expenses in advance or they must be insured through the Medicare program or have coverage through a verifiable third party insurance carrier. This financial policy relative to transplant patients is the same policy for all elective surgical admissions at the George Washington University Medical Center. Other countries, such as Great Britain, do have a policy which includes giving kidneys only to British citizens and sometimes citizens from the Commonwealth. The medical profession in the U.S. however, is completely different than that of Great Britain and it is the best in the world.

It has its own governing body and can take care of its own regulations and policies.

The decision of who gets the kidney and by whom is a very sensitive subject these days. There are many variables and considerations with each kidney transplant which must be specifically analyzed and applied to each patient. The medical expertise and experience needed in making these decisions cannot be replaced by any other person or body than the medical people involved. When a surgeon decides to put a kidney into his patient it is his moral, ethical and medical responsibility to take care of that patient. He spends his nights performing the surgery and the months after taking care of the patient. I feel that no one else should make the decision about which kidney goes to which patient other than the one who is performing the surgery and is ultimately responsible for the life of the patient and the outcome of the transplantation.

I hope I have answered some of your questions and I am ready to answer some more. Thank you very much for your time.

APPENDIX I

THE GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER
RENAL TRANSPLANTATION PROGRAM
POLICY MANUAL

Revised September, 1982

SECTION I

THE RENAL TRANSPLANTATION PROGRAM

I. THE RENAL TRANSPLANTATION PROGRAM

A. Philosophy of the Program

The George Washington University Medical Center's Renal Transplantation Program is dedicated to provide the maximum required direct and indirect health care services for patients suffering from end stage renal disease. As renal transplantation has become a widely accepted technique in the management of this disease entity, The George Washington University Medical Center has expanded its transplantation program to maintain a high level of competency in this area. The program is multidisciplinary in approach and provides comprehensive transplantation services to our patients. The Renal Transplantation Society and the Southeastern Organ Procurement Foundation in order to share our services with patients throughout the country and receive such reciprocity from other centers.

B. Organization For the Provision of Transplantation Services

1. Renal transplantation services are offered as an integral part of the End Stage Renal Disease Program at The George Washington University Medical Center. The End Stage Renal Disease Program is coordinated by the Dialysis and Transplantation Review Committee of the University Hospital medical staff. The committee consists of appropriate representatives from the clinical departments as well as other support members including the Tissue Typing Laboratory, Social Services Department, the Department of Nursing and the Medical Center Administration.

2. Inquiries should be directed to the responsible individuals listed on the insert of the current Medical Center staff.

C. Approvals and Affiliations

1. The End Stage Renal Disease Program is approved by:
   a. The United States Department of Health and Human Services
   b. The State of Maryland Kidney Commission
   c. The District of Columbia Department of Human Resources

2. The Tissue Typing Laboratory is approved by:
   a. The United States Department of Health Education and Human Services
   b. The District of Columbia Department of Human Resources
   c. The Center for Disease Control, Atlanta, Georgia
   d. The Southeastern Organ Procurement Foundation
   e. The American Association of Clinical Histocompatibility Testing

3. The Organ Preservation Laboratory is approved by:
   a. The District of Columbia Department of Human Resources as a licensed tissue bank.

4. Participating Dialysis Centers
    a. The Dupont Circle Dialysis Center, Washington, D.C.
    b. The Mid-Atlantic Nephrology Center, Camp Springs, MD
    c. The Greater Southeast Community Dialysis Unit, Washington, D.C.
    d. The Prince William Dialysis Center
    e. The Northern Virginia Dialysis Center, Arlington, VA

5. Affiliated Hospitals Participating in Cadaver Organ Procurement

    a. The George Washington University Hospital, Washington, D.C.
    b. The Children's Hospital National Medical Center, Washington, D.C.
    c. The Holy Cross Hospital, Silver Spring, MD
    d. The Mount Vernon Hospital
    e. The Alexandria Hospital
    f. The Northern Virginia Doctor's Hospital

SECTION II

PROTOCOL FOR CADAVER KIDNEY HARVEST

II. PROTOCOL FOR CADAVER KIDNEY HARVEST

A. Identification of Donors

1. General Policy

Each affiliated institution is encouraged to contact The George Washington University Medical Center Surgical Transplant Coordinator regarding any potentially suitable donor. The Surgical Transplant Coordinator determines donor suitability in accordance with the clinical criteria established in section B below and the protocols for clinical management of cadaver donors.

B. General Medical Criteria for Consideration of a Potential Cadaveric Kidney Donor

1. Absence of any infectious disease
2. Absence of any kidney disease
3. Absence of any malignancy (excluding the central nervous system; such patients may be acceptable donors)
4. Brain Dead in accordance with local governing statutes.

C. Brain Death

1. Brain death must be determined in accordance with the laws prevailing in each donor institution's jurisdiction and in accord with andy internal policies, procedures and/or regulations of the donor institution.

2. In the District of Columbia, the State of Virginia and the State of Maryland, the legal time of death is the time which brain death not cardiovascular cessation is certified by the attending physician.

   a. In the state of Virginia and the State of Maryland, pronouncement of brain death, by statute, requires that certification be performed by the attending physician and either a neurological or neurosurgical consultant.

   b. In the District of Columbia, brain death, by statute, requires certification by the attending physician only.

D. Judicial Clearance

1. The medical examiner in each donor institution's statutory jurisdiction must be notified regarding all cases which are defined as falling within his or her jurisdiction.

2. Those cases which commonly fall within the jurisdiction of the medical examiner are:

   a. Violent death of any type
   b. Death following surgery within twenty-four hours
   c. Death within twenty-four hours of admission to a hospital
   d. Homicide

   e. Suicide
   f. Death related to an injury where workman's compensation is involved.

3. While it is the attending physician's prerogative to initiate the legal clearance with the Medical Examiner, it is the responsibility of The George Washington University Medical Center Surgical Transplant Coordinator, after assessing the prospective donor, to manage and coordinate the formal obtaining of judicial clearance, including assurances that all necessary documentation and permits have been properly completed.

4. Once judicial clearance is obtained from the Medical Examiner, a progress note, minimally containing the following information is to be entered in the patient's permanent medical record by either the attending physician or the Surgical Transplant Coordinator:

   a. Date, time and Medical Examiner with whom the case was reviewed.
   b. Any specific limitations on the removal of tissue as specified by the Medical Examiner.
   c. Any specific instructions of the Medical Examiner regarding disposition of the body following kidney harvest.
   d. Any other pertinent judicial information or requirements provided by the Medical Examiner or other authorities related to the kidney harvest not otherwise specified above.

5. It is the responsibility of the George Washington University Medical Center Surgical Transplant Coordinator to insure that the directives of the Medical Examiner are subsequently carried out.

E. Contemporary Religious Positions on Organ Donation and Transplantation

   1. Most major religions, including Roman Catholicism, Protestantism and Judism approve and, in fact, encourage the donation of organs for transplantation.

   2. Whenever a question arises regarding religious tenets in this area, discussion with the family's religious counselor or minister may be helpful.

F. Permission for Organ Donation

   1. Prior to a potential donor's family being approached regarding the question of organ donation, it is essential that the donor's attending physician first concur in this action and that the attending physician be offered the opportunity to participate in obtaining permission from the family.

   2. The transplantation team will, if the donating institution's staff so desires, either assume responsibility for requesting the organ donation or assist the staff of the donor institution in making the request.

   3. The individual authorized to sign for permission for donation is the

legal next of kin as determined under applicable local statutes and internal policies and regulations.

4. If permission is obtained using an operative permit of the institution, the surgical procedure should be entered as "Cadaver Kidney Harvest, with specimens of spleen and lymph nodes for tissue typing."

5. In cases where the family wishes to donate multiple organs for removal at the same time as kidneys, each organ to be removed must be entered on the operative permit and such permission must be endorsed by the Medical Examiner, if the case falls within his jurisdiction. Examples of other organs which may be donated are: eyes, bone marrow, skin and heart.

G. Notification

1. When a potential organ donor is identified, The George Washington University Medical Center Surgical Transplant Coordinator should be notified by the institution where that donor is hospitalized.

   a. After assessing the prospective donor's status, the Surgical Transplant Coordinator will then notify other transplantation team members, as appropriate.

   b. The Surgical Transplant Coordinator may be contacted on a 24-hour-a-day basis, 7 days per week through the University Hospital page operator (202) 676-3321.

   c. In the event that the Surgical Transplant Coordinator cannot be reached, efforts should be made to notify the following in sequence until a response is obtained:
      1) Transplant Surgeon via the University Hospital page operator.
      2) On-call nephrologist via the University Hospital page operator.
      3) Tissue Typing via (202) 676-2797 or 676-3321.

III. Sequence of Events and Procedures in Cadaver Kidney Harvest

1. With The concurrence of the attending physician and following the pronoucement of brain death, the Surgical Transplant Coordinator performs an assessment of the donor's status.

   a. At the George Washington University Hospital, if the donor is not already located in a critical area, he is then admitted to one of the following areas in decreasing priority depending upon bed availability:
      1) Intensive Care Unit
      2) Recovery room
      3) General Surgical Unit

   b. It is recommended the donor institutions adopt similar protocols.

2. Permission from the Medical Examiner, if appropriate, and from the family is obtained, with appropriate coordination by the Surgical Transplant Coordinator, as previously described. Documentation of

proper brain death certification, required legal clearances and signed permission forms are also confirmed by the Surgical Transplant Coordinator at this time.

3. Once the donor has been assessed as being acceptable, the brain death pronouncement has occurred, and appropriate permission(s) has been obtained, all costs are thereafter borne by the Kidney Acquisition Cost Center of The George Washington University Medical Center, as authorized under Medicare regulations governing the End Stage Renal Disease Program.

   a. At the University Hospital, the Surgical Transplant Coordinator then effects a change of service for the donor to the GS-1 surgical service and completes the necessary financial reports to insure that appropriate billing from this point on is incurred by the Kidney Acquisition Cost Center.

   b. At other donor hospitals, this same reimbursement procedure is in effect for all cadaver donors. A formal change of service is individually determined in accordance with the internal policies and procedures at the donor hospital.

4. Once the patient has been pronounced brain dead, and the change of service has been effected, as appropriate, the clinical management of the donor up until the time of kidney harvest becomes the responsibility of the Surgical Service. Accordingly, the Surgical Transplant Coordinator is responsible for performing the following functions related to donor management:

   1. Write all patient care orders on the donor
   2. Implement those orders with nursing staff
   3. Perform needed medical treatment or minor surgical procedures, as indicated, and under direct supervision of the Transplant Surgeon.
   4. All orders written by the surgical Transplant Coordinator are to be countersigned by the Transplant Surgeon within 24 hours.
   5. Donor management is performed in accordance with the clinical protocols of the Renal Transplantation Program (available on request).
   6. The Surgical Transplant Coordinator also arranges for tissue typing, if necessary.

5. The Surgical Transplant Coordinator then schedules the kidney harvest with the operating room.

   a. Cadaver kidney harvests are considered emergency procedures and should be scheduled as such.

   b. Anesthesiology services are required throughout the surgical procedure for purposes of physiologic monitoring, administration of intravenous fluids and medications, and oxygenation.

   c. A listing of necessary anesthetics and surgical supplies, and protocols for irrigating and packaging the harvested kidneys are available on request.

6. The cadaver kidney harvest is then performed by the transplant surgeon or the surgeon designated by the donor hospital for this purpose. The Surgical Transplant Coordinator may act as first surgical assistant.

7. Upon completion of the kidney harvest, the body is wrapped and sent to the hospital morgue for disposition to the office of the Medical Examiner, where appropriate, or to the funeral home designated by the family. In Medical Examiner's cases, the Office of the Medical Examiner must be notified when the kidney harvest has been completed so that this office may make arrangements to transport the body. It is the responsibility of the Surgical Transplant Coordinator to insure that such notification is provided and to record in the donor's permanent medical record the time and with whom the arrangements were made.

8. A full operative report is dictated by the attending surgeon which is to be included in the permanent medical record. In Medical Examiner cases, the Medical Examiner must also be sent a copy of the operative report. Dictation should provide instructions to the Medical Records Department to transmit this copy.

9. The Surgical Transplant Coodinator is responsible for organ preservation and disbursement in accordance with policies and procedures of the Southeastern Organ Procurement Foundation, and the organ preservation manual of The George Washington University Medical Center (available on request).

10. A letter of thanks to the donor's family and participating staff (with appropriate comments as to outcome) is prepared and transmitted by the Surgical Transplant Coordinator.

SECTION III
PROTOCOL FOR LIVING RELATED DONORS

III. Protocol For Living Related Donors

A. General Policy

Living related donor transplantation is encouraged whenever possible, since the current clinical state of the art of histocompatability testing and transplantation demonstrates a higher success rate and longer graft survival. If a living related donor is available, the reduced waiting period for transplantation and the opportunity for coordinated planning constitute signficant additional advantages.

All living related donors must be informed and voluntary participants. Transplantation is performed only after detailed physical and psychosocial screening of the prospective donor and recipient.

B. Medical Criteria for Selection of a Living Related Donor

1. Appropriate Blood Type (ABO, Rh)
2. Lewis Phenotype
3. Histocompatibility Testing
    a. Histocompatibility Human Lymphocyte Antigen (HLA) Locus Antigen Tissue Typing
    Best match in order of preference is:
    4 Antigen Match
    3 Antigen Match
    2 Antigen Match
    1 Antigen Match
    0 Antigen Match
    b. Dr Locus Antigen Tissue Typing match.
    c. The absence of previously determined unacceptable antigens for the recipient in the donor's antigen profile.
    d. Mixed Lymphocyte Culture Compatibility, when appropriate.
    e. Final negative cross match (as an inpatient) one day prior to transplant

4. General Me[illegible] [illegible]tus: No chronic or acute illnesses

5. Absence of:
    a. Infectious disease
    b. Extracerebral malignancy
    c. A known potential for hereditary kidney disease

6. Normal urologic evaluation based on:
    a. Physical examination
    b. Cystoscopy
    c. Intravenous pyelogram
    d. Renal arteriography

7. Psychological preparedness

C. Sequence of Events in the Evaluation of a Living Related Donor

If the prospective donor and the Transplantation Program's attending physicians so desire, physicians not affiliated with The George Washington University Medical Center Transplantation Program may perform the clinical assessments described, provided that all required reports are forwarded to the Transplantation Program, C/O Division of Renal Diseases (nurse practitioner), and that these reports meet the standards set forth by the Transplantation Program.

1. Stage One:

   a. Education and counseling of the potential donor by his private physician or Transplantation Program physicians regarding the potential organ donation.

   b. Patient agrees to be evaluated as a potential donor.

   c. Meeting of potential recipient, his/her family (with potential donors), nephrologist, nurse practitioner, social workers and representative of nursing staff on GS, the purpose of which is to explain procedure, answer questions, assess family dynamics, and set up appointments for stage two if family wishes to proceed.

2. Stage Two:

   a. Blood Typing (ABO,Rh)
   b. Histocompatability Testing
      1) Histocompatibility locus antigens
      2) Mixed lymphocyte culture

3. Stage Three: Complete medical evaluation

4. Stage Four: Psychological evaluation

5. Stage Five: Urologic evaluation using criteria described above. (Renal arteriography is also performed, however, not until one day prior to surgery.

6. Stage Six:

   a. Synthesis of all data into a composite summary by the nurse practitioner of the Division of Renal Diseases.

   b. Surgical evaluation by the Transplant Surgeon and Surgical Transplant Coordinator.

7. Stage Seven: Patient is presented to the Dialysis and Transplantation Review Committee for final approval prior to transplantation, or for further evaluation as indicated by the individual case.

D. Patient Care For The Living Related Donor

1. The living related donor is admitted to the service of the participating urologist at The George Washington University Hospital.

2. Responsibility for clinical care during this period and for long term outpatient care rests with the urology service. Responsibility for long term outpatient care may be delegated to a private urologist of the patient's choosing.

3. Social worker available for emotional support of donor and other family members as needed during hospitalization and for 3 months following discharge.

E. Financial Responsibility for Care of the Living Related Donor

1. Costs incurred in evaluation, hospitalization, and post-hospitalization care, including physicians' fees, which are consequent to the living related donor transplantation are borne by the Kidney Acquisition Cost Center of The George Washington University Medical Center as authorized under Medicare regulations governing the End Stage Renal Disease Program.

2. It is the responsibility of the Surgical Transplant Coordinator to insure that appropriate George Washington University Medical Center financial forms are properly completed in accordance with approved policies and procedures.

SECTION IV

PROTOCOL FOR RENAL TRANSPLANT RECIPIENTS

IV. PROTOCOL FOR RENAL TRANSPLANT RECIPIENTS

Patients undergoing renal transplantation at The George Washington University Medical Center proceed through several stages of evaluations and patient care, with clinical responsibility assigned as described.

Patients referred for transplantation are those under the care of The George Washington University Medical Center Division of Renal Diseases, affiliated dialysis centers, or private physicians.

Certain of the following clinical assessments may, at the discretion of the Transplantation Program physicians, be performed by physicians not affiliated with The George Washington University Medical Cancer Renal Transplant Program. Under such circumstances, however, necessary clinical reports must be forwarded to the nurse practitioner of the Division of Renal Disease, and meet the standards set forth by the Transplantation Program.

A. Sequence of Events In Evaluation of a Potential Recipient

1. Stage One:

    a. Patient is under the care of his private physician and is maintained on hemodialysis or peritoneal dialysis.

    b. Initial education and counseling of the potential recipient is undertaken regarding transplantation until such time as the patient makes a decision to proceed with transplantation or to maintain his current dialysis program.

2. Stage Two:

    a. Patient is referred to The George Washington University Medical Transplantation Program for initial preoperative assessment.

    b. Initial referral may be to any participating physician in the Transplantation Program. However, the synthesis of data and renal evaluation for purposes of assessing transplant potential is to be performed by The George Washington University Medical Center Division of Renal Diseases.

    c. Meeting of potential recipient, his/her family, nephrologist, nurse practitioner and renal social workers; the purpose of which, is to explain procedure, assess family dynamics and set up appointments for stage three.

3. Stage Three:

    a. Blood typing (ABO,Rh)
    b. Histocompatibility Testing
        i) Histocompatibility locus antigens
        ii) Mixed lymphocyte culture (if the patient is being considered for a living related transplant).

4. Stage Four:

a. Complete medical evaluation
b. Renal evaluation to include:
   1) Review and recommendations for current clinical management and maintenance dialysis
   2) Renal biopsy
   3) Consideration of alternative therapeutic modalities, if indicated; for example, home dialysis

5. Stage Five: Psychological evaluation

6. Stage Six: Urological evaluation including physical examination and cytoscopy.

7. Stage Seven: Dental evaluation

8. Stage Eight:

   a. Synthesis of all data into a composite summary by the nurse practitioner of the Division of Renal Disease.

   b. Surgical evaluation by the Transplant Surgeon.

9. Stage Nine: Patient is presented to the Dialysis and Transplantation Review Committee for final approval prior to transplantation, or for further evaluation as indicated by the individual case.

10. Stage Ten:

   a. If a living related donor transplant is agreed upon, arrangements are provided for as described in section B below.

   b. If a cadaver donor transplant is agreed upon, the potential recipient is entered into the United Network For Organ Sharing Computer Match Program through the computer terminal located in the Tissue Typing Laboratory of The George Washington University Medical Center, until a suitable kidney becomes available for transplantation.

   c. Up until the time of transplantation, the potential recipient is cared for by the attending nephrologists of The George Washington University Medical Center and the private physician, or by the community dialysis and staff who have referred the patient. Affiliated dialysis center staffs update the current medical status of potential recipients at least monthly with the Transplantation Program through direct communication with the nurse practitioner of the Division of Renal Diseases.

   d. Procedures for admission and delineation of clinical responsibilities are described in section B below.

11. Stage Eleven: Transplantation is performed at The George Washington University Hospital. The recipient is under the care

of the Surgical Service, with consultation from the Division of Renal Diseases during the period of hospitalization.

12. Stage Twelve:

    a. After discharge from the hospital, the recipient is usually referred for long-term postoperative care and management of immunosuppressive therapy to the Division of Renal Diseases with consultation from the Surgical Service.

    b. A recipient referred from an affiliated dialysis center or private physician may, if he and his private physician so desire, return to his own private physician for postoperative care. However, in the interests of quality patient care, determinations as to such referrals should be made on a case by case basis and should be based on a joint decision involving the Transplant Surgeon, the attending nephrologist of the Division of Renal Diseases, the private physician and the patient.

    c. The term "attending nephrologist" refers to the full-time faculty member of the Division of Renal Diseases who is assigned to the inpatient service for the month in which the recipient was transplanted and who actively participated in the recipient's clinical care during the course of his hospitalization before, during and following transplantation.

    d. For those recipients who return to their private physician for post operative care, it is requested that monthly reports be submitted to the nurse practitioner of the Division of Renal Disease. These reports should include the following information:

        1) Renal function, as reflected by urinary output, serum creatinine and creatinine clearance.

        2) General medical status.

        3) Immunosuppressive therapy, including drugs, dosage, clinical response and complications, if any.

        4) Surgical and/or urologic complications, if any. In such patients, the attending nephrologist and transplant surgeon are available to provide consultative services, if requested, or to assume direct responsibility for patient managment.

        5) General emotional well-being regarding compliance with treatment plan.

B. Procedures for Transplantation at The George Washington University Hospital

    1. Living Related Donor Transplantation

a. Coordination of living related donor transplantation, including arrangements for admission, surgical posting, intensive care unit reservations and completion of required financial reports is the responsibility of the nurse practitioner of the Division of Renal Diseases.

b. Both the donor and the recipient are admitted to Nursing Unit 6-South in The George Washington University Hospital, but not necessarily to the same room.

c. Recipients are admitted to the Surgical Service, which assumes primary responsibility for the care of the patient.

d. Donors are admitted to the Urology Service which assumes primary responsibility for the care of the donor.

e. Clinical care for both the recipient and donor is provided in accordance with the clinical protocols of the Renal Transplantation Program (available on request).

2. Cadaver Donor Transplantation

a. Upon notification of the surgical Transplant Coordinator that a kidney is available for a recipient on the waiting list of The George Washington University Medical Center Transplantation Program, he is responsible for the following tasks:

1) Notification of the Transplant Surgeon and the attending nephrologist (or the private physican or nephrologist of the potential recipient) as to the availability of a kidney and the clinical data pertinent to organ retrieval.

2) Assisting the Transplantation Surgeon and other responsible physicians in assessing the acceptability of the available kidney. The Transplant Surgeon is responsible for making the final determination.

3) Notification of the potential recipient.

4) Coordinating the following arrangements:

1- Hospital admission (preferably to Nursing Unit 6-South).
2- Intensive care unit reservation
3- Surgical posting (cadaver donor Transplantation is considered as an emergency procedure and should be scheduled with the operating room as such).
4- Anesthesia preoperative consultation
5- Tissue Typing for final crossmatch

5) Providing for appropriate transport of the kidney in accordance with the guidelines of the Southeast Organ Procurement Foundation and performing organ preservation procedures as necessary in accordance with The George Washington University Medical Center Organ Preservation

Manual and the guidelines of the Southeastern Organ Procurement Foundation.

C. Financial Responsibility for Care of the Transplant Recipient

1. Costs incurred in evaluation, hospitalization, and post hospitalization care, including physician's fees, which are consequent to renal transplantation (living related donor or cadaveric) are borne by the Kidney Acquisition Cost Center of The George Washington University Medical Center as authorized under Medicare regulations governing the End Stage Renal Disease Program.

2. It is the responsibility of the Surgical Transplant Coordinator to insure that the appropriate George Washington University Medical Center financial forms are properly completed in accordance with approved policies and procedures.

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TIME: 10:28:24      DATE: 10/24/83

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2 2              DCWH 0  35FC 1    1 32 51 16  4 61 -+  00:00  8305
1 2              DCWH 0  34MC 2   28 30 51 --  4 61 -+  71:71  8307
1 2              DCWH 0  31FC      1 26 17 44  3  4 +-  06:06  8307
1 2              DCWH 0  35FC 1    2 26 51 38  2  6 +-  24:24  8305
1 2              DCWH 0  36FB 1    1 11 55 17  4  5 +-  84:84  8308
1 2              DCGU 0  29MC 1    2 29 45 --  2 61     00:00  8310
1 0              DCGW 0  26MC 1    3 24 15 35  2 -- -+  83:00  8302      U
1 0              DCWH 0  35FC 2    2 24 44 --  2  4 +-  70:13  8208
3 2              DCWR 0  32FC 2 H  2 -- 44 --  4  7     99:96  8112      U
1 2              DCWH 0  36MC 1    2 --  7 35  2  4 +-  09:09  8309
2 0              DCWR 0  33FC 1   24 11 38 60 -- --     90:55  8210      U
1 1              DCWH 0  57MB 1   23 34 17 35  5 -- -+  29:09  8011
2 2              DCWH 0  37FB 1   23 28  5 35  2  3 --  00:00  8301
1 0              DCGU 0  42MB 3    3 34  7 60  2  6 --  99:99  8303
1 0              DCCH 0  11FB 1 H  3 --  8 22  5  7     00:00  8305
2 0              DCWH 0  36MB 2   32 36 35 52 -- -- -+  60:50  8103      U
2 2              DCWR 0  24FC 2    1  3  8 --  3  4     99:99  8201      U
1 0              DCGW 0  46FC 3 H  1 11 15 35  6  7 +-  67:28  8205      U
1 0              DCWH 0  29MB 2   24 25  7 35 61 --     99:71  7901      U
1 0              DCGW 0  38FB 1   28 11  5 35  1  9 -+  00:00  8308      U
2 0              DCHU 0  22MB 3   10 29 35 -- -- --     74:10  8106      U
1 1              DCWH 0  27FC 2    1 32 35 --  2 -- +-  21:21  8302
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1 2              DCWH 0  25MB 1    1 33  7 44  5  8 --  54:06  8205
1 1              DCHU 0  38MB 1   30 32 -- --  5  8     90:90  8305
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1 2        DCGU O  20MB 1   23 26 41 45   7  9 --  18:00  8306
1 2        DCWH O  22MB 1   28 31 17 42   2  3 -+  08:06  8303
2 2        DCWH O  56MB 2   28 33 17 35   6  8 +-  37:09  8205
2 1        DCHU O  39MB 1   30 --  5 22   5  7     11:--  8104
1 0        DCGW O  36MB 1   23 30  7 42   3  5 +-  10:10  8310     U
2 3        DCGW O  39MB 2    2 30  5 14  -- --     68:--  8003     U
1 2        DCGU O  48MB 1 H 23 28 41 45   2  6 -+  10:06  8207
1 2        DCWH O  32MB 1    2 29 15 44   5 10 -+  06:06  8305
1 2        DCWH O  34MB 1   28 36 15 17   6  7 +-  29:15  8210
1 0        DCGU O  29MC 2    2 -- 14 44   1  4 -+  88:28  8102     U
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1 0        DCCH A  20FC 2 H  2 28 12 17   2  6     80:66  8305     U
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2 4        DCWR A  31FC 2    1  3  8 27   3 --     53:45  8208     U
1 2        DCGU A  49FB 1 H  2 --  8 45   4  8     75:38  8308     U
1 2        DCGW A  41MC 2    2 --  8 14   1  3 -+  03:03  8310     U
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2 0        DCWR A  60FC 2    2 -- 13 15   2 --     99:38  8109     U
1 2        DCWH A  47MB 1    3 31  7 18   2  3 -+  55:15  8303
1 0        DCGU A  20FB 3    2 23  8 14   3  7 -+  99:94  7801     U
2 2        DCWR A   9MC 4    2 33 44 37  -- --     97:38  8109     U
2 2        DCWH A  36MB      2 23 45 27   4  7 -+  06:06  8309
2 2        DCWH A  40MB      2 30 44 17   2  6 -+  03:03  8309
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3 4        DCWR A  12MB 2    3 26 17 60   1  6     32:01  8210     U
2 2        DCGW A  47MB 1    1 29 50 40   7 --     15:00  8301     U
2 2        DCWH A  22MB 1    2 33  7 49   4  5 +-  00:00  8306
1 2        DCCH A  17FB 1 H 23 -- 44 42   1 --     03:00  8306
1 2        DCWH A  43MB 2    2 30 12 --  61  8 --  50:37  8306
1 4        DCGU A  29MB 2   28 33 15 49   3  7 -+  00:00  8310
1 4        DCGU A  19MC 1    1 24  8 51   3  5 -+  00:00  8306
1 2        DCGU A  61MC 1   29 -- 14 45  61  7 -+  0 :0   8308
1 2        DCWH A  51MB 1    1  9  7  8   2  3 -+  12:12  8310
2 2        DCWH B  34MB 3    3 32 12 35   5  6 --  97:62  8204
2 4        DCWH B  32MB 2    2 26 35 17   3 61 --  95:00  7808     U
2 2        DCWH B  42FC 1    1 34 14 17   4  7 -+  68:03  8205
2 0        DCGW B  23MB 1   36 26 17 18   3  7     20:00  8003     U
2 0        DCGU B  33FB 3    2 33  7 35   2  3 -+  73:49  8303     U
2 0        DCGU B  16MC 1 H  1 24 35 50   4  6     97:60  8306
2 0        DCGW B  52MC 1   24 31 12 42   5  6 -+  14:14  8302     U
2 2        DCWH B  28MC 2    3 11 39 27   2  7     44:44  8302
3 2        DCWR B  34FB 1   29 30 17 35   4  6     05:05  8309
1 2        DCWH B  33MB 3   30 32  7 40   2 -- -+  58:18  8301
2 2        DCWH B  34MB 2    1  2  7 ·8  -- --     96:33  7910
3 2        DCWR B  51MC 1    3 32 35 35   1  5     95:49  8309
1 2        DCGU B  48FC 1   24 31  7 39   2  4 --  99:99  8308
1 4        DCWH B  28MB 3    2 26 21 35  -- -- -+  99:93  7910     U
2 0        DCWR B  44FB 2    2 26  7 39  -- --     89:86  8301     U
1 0        DCGU B  25FB 4    2  3  8 --   4  7 --  98:81  8008     U
1 2        DCWH B  45MB      2  3 12 57   4  5 --  11:06  8309
2 0        DCGW B  25MO 1   11 26 46 59  -- --     95:58  8202     U
2 2        DCCH AB  9FC 2 H 28 29 27 35   2  5     77:00  8309     U
2 4        DCWR AB 21MB 3   30 33 17 35   6 -- --  99:87  8102     U
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U = UNACCEPTABLE ANTIGENS

PATIENT NAME     ===========A/B===========   ===DR===  =BW=  ===CW===

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                 10 31 32 33  2 28
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                  2 28 32 15 25 17  5 42    2
                  3 23 16
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                  3 32 12 30  7 42
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                  3 12
                  2 29                      3  7
                 28 45 51                   1
                  2  3  5 14
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                  9  5 35  1
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                 23 18
                  3 11 44                   7
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COMMAND:  S

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OFF AT 10:37:15   10/24/83
GOODBYE
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APPENDIX III

THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Department of Urology
(202) 676-4002

The H B Burns Memorial Building / 2150 Pennsylvania Avenue N.W. / Washington, D.C. 20037

ORGAN PROCUREMENT HOSPITAL DESIGNATIONS - WASHINGTON AREA TRANSPLANT SOCIETY JUNE 1982

- GWUMC
  - GWUH
  - Holy Cross
  - Alexandria
  - Northern Virginia Doctors
  - CHNMC
  - Mount Vernon Hospital

- WHC
  - WHC
  - P.G. County
  - P.G. Doctors
  - Shady Grove
  - Greater Laurel - Beltsville
  - Washington Adventist
  - Montgomery General
  - Capital Hill

- GEORGETOWN
  - GUH
  - Sibley
  - Fairfax
  - Winchester
  - Circle Terrace
  - Potomac
  - Jefferson Memorial
  - Southern Maryland

- HOWARD
  - HUH
  - D.C. General
  - St. Elizabeth's
  - Hadley
  - Providence

- WALTER REED
  - Walter Reed
  - Bethesda
  - Ft. Belvoir
  - Suburban
  - Greater Southeast
  - East Coast Military Hospitals
  - NIH

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CURRENT REFERRAL BASIS FOR WASHINGTON AREA TRANSPLANT PROGRAMS - JUNE 1982

GWUMC

G.W. Renal Division
MidAtlantic Dialysis Center
Northern Virginia Dialysis Center
Greater Southeast Hospital (Two Nephrologists)

GEORGETOWN

Georgetown In-hospital Unit
Bethesda Dialysis Center
Fairfax BMA Dialysis Center
Arlington BMA Dialysis Center
Capital Hill BMA Dialysis Center
Greater Southeast Hospital (Two Nephrologists)
Martinsburg (W. Va.) Hospital Dialysis Center

WHC

WHC Renal Division
MidAtlantic Dialysis Center
Dupont Circle Dialysis Center

HOWARD

Howard University Renal Division

CHNMC

Renal Division, CHNMC

APPENDIX IV

THE
GEORGE
WASHINGTON
UNIVERSITY
MEDICAL CENTER

Department of Urology
(202) 676-4002

The H.B. Burns Memorial Building / 2150 Pennsylvania Avenue N.W. / Washington, D.C. 20037

The following financial information is based on an estimate of the hospital and professional charges associated with kidney transplant surgery at The George Washington University Medical Center. These charges are valid through June 30, 1984.

Pre-Transplant Outpatient Care

Professional Fees	Maintenance Dialysis	$ 300.00	month
Hospital Charges	Maintenance Dialysis	2,475.00	month
		2,775.00	
Note: Patients awaiting transplant surgery may require dialysis for 6 months or longer prior to surgery.		x 6	
		$ 16,650.00	Total

Inpatient Care

Professional Fees	21 Physician Visits	$ 735.00
Professional Fees	6 Acute Dialysis Treatments	2,700.00
Professional Fees	Surgeon (for recipient)	6,000.00
Professional Fees	Surgeon (for donor)	6,000.00*
Hospital Charges	Average 21 Day Stay	54,000.00**

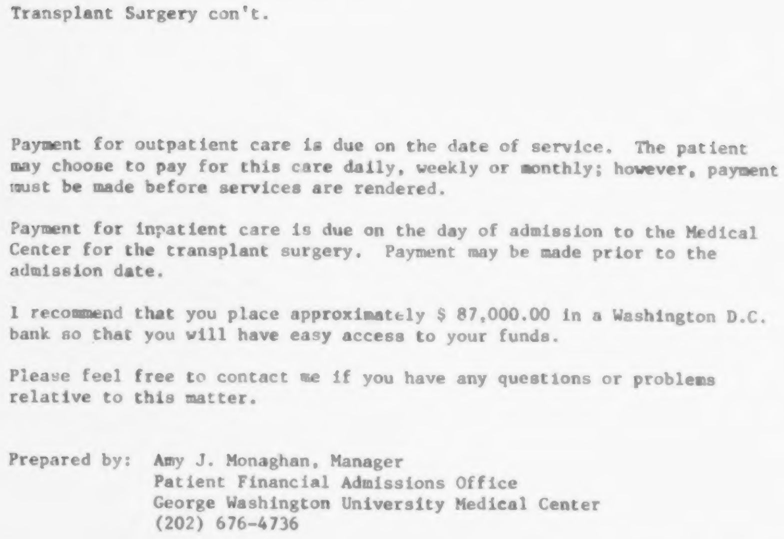
* Deduct if not a live donor
** Includes all Facility charges associated with the surgery as well as the kidney acquisition charges

Follow-Up Care

Professional Fees	Transplant Clinic Visit	$ 35.00	each
	Urinalysis	15.00	each
		50.00	
Note: Following surgery, the patient may require as many as 15 Transplant Clinic visits.		x 15	
		$ 750.00	Total

Summary

Outpatient Maintenance Dialysis	$ 16,650.00
Inpatient Professional Care	15,435.00
Inpatient Hospital Charges	54,000.00
Transplant Clinic	750.00
Total - This is an Estimate	$ 86,835.00



Transplant Surgery con't.

Payment for outpatient care is due on the date of service. The patient may choose to pay for this care daily, weekly or monthly; however, payment must be made before services are rendered.

Payment for inpatient care is due on the day of admission to the Medical Center for the transplant surgery. Payment may be made prior to the admission date.

I recommend that you place approximately $ 87,000.00 in a Washington D.C. bank so that you will have easy access to your funds.

Please feel free to contact me if you have any questions or problems relative to this matter.

Prepared by: Amy J. Monaghan, Manager
Patient Financial Admissions Office
George Washington University Medical Center
(202) 676-4736

Mr. GORE. Thank you very much. We appreciate your testimony.

Dr. Schreiner, we are certainly honored to have you with us here today. We have sworn all witnesses in during this investigative hearing and you missed the beginning of the panel. I trust you won't mind if I ask you to stand and raise your right hand.

Do you solemnly swear the testimony you are about to give will be the truth, the whole truth, and nothing but the truth, so help you God?

Dr. SCHREINER. I do.

Mr. GORE. Thank you very much. Without objection, the entire text of your prepared statement will be included in the record. If you wish to summarize any portion of your statement, feel free to do so. Please proceed.

Dr. SCHREINER. Thank you very much, Mr. Chairman. I really appreciate the opportunity of coming here, and I think your committee has done a great service in shedding light on this very important topic which worries people, and I think simply presenting the facts may be a very, very constructive operation just for its own sake because I think there is a lot of misunderstanding about it.

As you mentioned, I have prepared a full statement and that will stand in the record. I would like to comment on a couple of things.

One of the things I would like to remind—I think we sometimes forget—and that is what is the basic legal status of a cadaver kidney and also to point out that in the case of live donor donation, there is no competition with anything and we should try to do as many of these as we possibly can. I personally feel that every dollar the United States spends in this area is perhaps worth thousands of foreign aid dollars that get sprinkled around. My experience is the individuals who are helped by medicine in the United States are grateful for long periods of time and that this may be one of the best ways that we could possibly engender good will among other nations in the world. And I could tell you many personal stories I have to illustrate that, including one time when a general strike was called off in Chile preceding an election just because the patient was treated by us.

The important point to remember is that the disposal of a part of the body in the United States was a State matter and was regulated by and large, in those State legislatures that had laws, by the British common law which goes back to the 1832 British Tissue Act, except for Louisiana, which follows the Napoleonic code. That treated the body essentially as chattel and it belonged to the next-of-kin, so that an individual was unable to donate his own body—he could do anything he wanted with his money, but he couldn't do anything that he wanted with his body.

This was changed by the Uniform Donor Code Act, which came about initially as a result of a committee set up by Dr. James Shannon at the NIH, and then eventually enlarged into a council of scientific societies and medical societies that were concerned with this problem. I happened to represent the National Kidney Foundation on that council.

The Uniform Donor Act, and the language of the card which we actually devised and wrote, was done with consultation of many experts from all the major religions and some of the great experts in constitutional law in the United States. The point was that we changed the basic ownership of the kidney from the next-of-kin to the donor himself, if he so chose. This suggests to me that we now have a strong ethical and legal background that the cadaver kidney, in fact, belongs to the donor and certainly not to the State. So I think that we must be very careful in not fracturing this ethical and legal history.

It's my firm belief that a rigid policy for who gets the kidney is not workable nor enforceable. If Congress so desires, our general philosophy could be incorporated into a guideline, namely, that we should make our facilities available on a traditional American basis of compassion so long as adequate consideration is given to American recipients.

The presence of non-Americans on the list, in fact, increases the efficiency of distribution of organs and reduces the number of donated organs which might otherwise go unused or unmatched. We must remember that when someone signs an organ donor card, or the form on the back of a driver's license, he basically is making a contract with society, which contract may not be fulfilled for many, many years, many decades, in fact, we hope, and I think those of us who work in this field must be aware of that contract and, to my mind, the most immoral thing is to have an organ donated and not have it used. So I think that we are obligated to have a system which provides for maximum utilization and maximum distribution.

In our recent experience, this holds true when we give first consideration to Americans, but at the same time keep foreign, nonimmigrant aliens who are able to come to this country for help on our lists in order to keep the recipient list as long and as diversified as possible with respect to HLA antigens and ABO antigens.

I hark back again to the person who gave this kidney. He wanted his organs to be used. He also could specify on the organ donor card for whom he wanted them used. I could see a scenario, for example, where a Greek restaurant owner might very well dedicate his kidney to a Greek national, and it would be quite an interesting theoretical conflict if we had legislation on the books that prevented us from transplanting a Greek national while on the other hand we had a kidney that was donated for the purposes of being transplanted into a Greek national.

Mr. GORE. Let me clarify, Dr. Schreiner, before you proceed, that we're not considering a law to make it illegal to transplant nonimmigrant aliens. This is an investigative hearing to look at the nature of the problem and explore the perception of a problem that has arisen. But we don't have a specific law regarding this that's before us. But please proceed.

Dr. SCHREINER. Being familiar with your liberal background, Mr. Gore, I wouldn't have expected that you would, but I wanted——

Mr. GORE. Let me hasten to defend myself.

Dr. SCHREINER. I wanted to put that in in case someone is tempted to be so restrictive as to really, I think, interfere with the operation of our system.

I do think that we create good will. We also create interest in organ donation among the diverse ethnic groups in our population. We have noticed, for example, we have a particular agreement and affiliation with the Greeks in the division of nephrology, and this has come about for reasons of a very long kind of interrelationship. And we have noticed a marked improvement in the attitude, for example, of the Greek Orthodox Churches and the 65,000 ethnic Greeks who live in the Washington area as a result of this program which has now been operating for a number of years.

I would also like to point out that there are very few countries that have the medical manpower or the surplus transplant capabilities such as we have in the United States. Great Britain appeared to transplant nonresident aliens with great freedom and flexibility until they were done in by the media and BBC ran a program questioning the criteria for brain death. This produced a mild panic in the British population. They tore up organ donor cards by the thousands and the transplantation system was dealt a very severe blow, including a marked diminution in the rate of transplantation, and in some cases they found patients sitting on their lists for periods of several years whose clinical situation was deteriorating. In fact, we were sent one or two such individuals out of desperation.

I feel it is extremely important, therefore, to have a liberal program. On a purely service basis, Washington's transplant capability can easily serve its indigenous population, its military needs, and our current level or perhaps even a slightly increased level of foreign transplants. The benefits and political good will of such a compassionate policy are particularly visible and evident in our international community.

The presence of foreign embassies in Washington for support services renders it the natural place for such transplants to be centered. Washington is, after all, the international capital of the world. We maintain a large recipient list; we increase the efficiency of distribution and we render a higher percentage of donated organs to be useful and actually used.

We must also remember that so long as they are fully paid for, they are sharing the fixed costs of running a transplantation and an organ procurement program, and they are also sharing indirectly some of the costs of research and clinical investigation which go on continuously in the field of transplantation, which as you know is ever-changing.

So I feel that actually the number of foreign transplants we do is a very reasonable one. It helps share costs, it helps share costs for the university, for the hospital, and for the U.S. taxpayer.

I thank you very much for the privilege of speaking.

[The prepared statement of Dr. Schreiner follows:]

TESTIMONY ON
ORGAN TRANSPLANTATION IN INTERNATIONAL PERSPECTIVE: ETHICAL ASPECTS

Before The
Subcommittee on Investigations and Oversight
Committee on Science and Technology

U.S. House of Representatives

Washington, D.C.
November 7, 1981

By

George E. Schreiner, AB, MD, FACP
Professor of Medicine
Georgetown University School of Medicine
Washington, D.C.

November 1, 1983

WRITTEN STATEMENT OF GEORGE E. SCHREINER, AB, MD, FACP
PROFESSOR OF MEDICINE, DIRECTOR DIVISION OF NEPHROLOGY
Georgetown University School of Medicine

MR. CHAIRMAN:

I am Dr. George E. Schreiner, Professor of Medicine and Director of the Nephrology Division at Georgetown University School of Medicine. I have been engaged full-time in the scientific and clinical study of the kidney for the past 37 years. A summary curriculum vitae and list of organizations is attached and available with this statement. I would simply point out by way of highlighting that in the medical field I was a founding member, secretary and president of the American Society of Nephrology; president of the International Society of Nephrology; president of the American Federation for Clinical Research; president of the Southern Society for Clinical Investigation; president of the American Society for Artificial Internal Organs and Editor of its journal, THE TRANSACTIONS OF THE ASAIO for 26 years; president of the National Kidney Foundation and the Washington Heart Association. I am currently president of the American-Israel Society of Nephrology.

In terms of my background in ethics, I was a philosophy major with special studies in ethics, on the committee for the Code of Ethics for the American Society for Clinical Investigation, the National Drug Research Board of the National Science Foundation, the Advisory Council of the Food and Drug Administration, Study

Section A of the National Institutes of Health, the White House Uremia Commission, and Consultant to the Kennedy Center for Bioethics at Georgetown. I have been chairman of the Nephrology Grants and Training Review Committee for the Veterans Administration and the New York State Kidney Institute. I was a founding member and served for more than a decade on the Human Research Review Committee of Georgetown University which existed even before the Human Research Review Committees were mandated by the FDA and the NIH. I hold memberships in the Medical Societies of Peru, Chile, Costa Rica, Argentina, Paraguay, Japan, South Africa, Australia, and the Kidney Foundation of the Philippines. I was the National Kidney Foundation representative to the Advisory Group that devised the Uniform Donor Card and I was the Legislative Chairman of the National Kidney Foundation who worked on the Medicare Legislation which Senator Long introduced to qualify patients with end-stage renal disease as disabled under the Entitlement Program of Medicare. All this adds up to an intense personal interest in scientific and clinical matters of nephrology and the ethical aspects of all phases of kidney disease and its treatment and a strong interest in International Medicine.

Georgetown University School of Medicine has operated a kidney clinic under my direction since 1951 and a Division of Nephrology since 1952. A kidney transplant program was begun in 1964. We were founding members, and have continuously supported the Southeastern Organ Procurement Foundation (SEOPF) which was originally established by a grant to Dr. David Hume in Richmond, Virginia in 1969. In recent years our transplantation program at Georgetown has been designed with a goal of approximately 50 transplants per year. In 1981 - 39 actual transplant operations were performed, three of them in non-immigrant foreign nationals. In 1982 - 45 transplants were performed, 14 in non-immigrant foreign nationals from seven different countries. Thus far in 1983 - 45 transplants have been performed and included 15 non-immigrant foreign nationals from six different countries. Our annualized rate extrapolated for the remainder of 1983 will be approximately 55 kidney transplants.

At the outset I would like to make some major points clear which may be confused in the minds of laymen. In the case of live-donor transplants they are never in competition for kidney supply since they are living-related individuals. These patients are accepted by us from a referring physician regardless of sex, race, creed, religion or country of origin. Strict bioethical procedures are followed regarding informed consent, the insurance of true volunteerism on the part of the potential donor and a thorough medical and immunologic workup of all potential donors to make sure that we have the best suitable transplant from a truly volunteered donor. Live donor transplants are then scheduled essentially when they are ready to go.

The second major point, which is often confused, is that large transplant programs have a number of fixed costs which have to be shared by the total number of transplant operations performed if charges are to be kept uniform. The cost per transplant, for example, is enormously prohibitive to the United States taxpayer if less than 10 transplants per year are performed. The addition of 10 living-donor foreign transplants would cut the fixed costs to the United States taxpayer in half. Thus, living-donor transplantation for foreign nationals is unequivocably and unqualifiedly non-competitive with American patients and, quite the opposite, is highly cost-effective in reducing the fixed cost of these programs to the American taxpayer.

Cadaveric transplants pose a different set of questions. First in the broader legal and ethical question of who is the owner of the kidney? It is my impression that virtually every state in the Union followed English common law with the possible exception of Louisiana which follows a Napoleonic code. English common law was based on the 1832 British Tissue Act which established the cadaver essentially as part of the inheritance following the death of the individual. In a way the body was chattel and the law disposed of it and its parts as if it were owned by the next of kin. This legal situation was substantively reviewed by an Advisory Committee appointed by Dr. James Shannon when he was director of the National Institutes of Health. This committee enlisted an Advisory Council from major organizations interested in the problem and I represented the National Kidney Foundation on that Council. We had many consultants from prestigious law schools and the cooperation of the American Bar Association Committee on Uniform Code. The end result of the work of that Commission was the development of a law which has become known as the Uniform Donor Act and a card, which may be carried in the wallet, and which is printed on the back of a number of state driving licenses. The Uniform Donor Act was introduced in every state legislature in the land and was ultimately passed by all 50 states within less than three years of its introduction -- a fitting tribute to its acceptance by a clear majority of the American people. The Uniform Donor Act essentially allows a person who dies to will his kidneys and this becomes a legally final act if he is carrying a Uniform Donor Card properly executed on his person at the time of his death. There is a place on the Uniform Donor Card which is entitled "other" which is intended for the donor to put in any restrictions on organs donated or any restrictions on the use thereof. It seems to me to be pretty clear from both the legislation and legislative history that the Uniform Donor Act allows the living or dying person to own his own kidney. In any event, the legal status of cadaveric organs,it seems to me, is quite clear. The organ is owned either by the individual if he donates it by way of an Organ Donor Card or it is owned by the next of kin if he fails to do so. There is no precedent that I know of which states that the kidney is owned by a city, by a state, or by the federal government. This legislative history must be made crystal clear in light of the legislation which is the subject of today's hearing. I could envision a scenario for a horrible and basic conflict if a dying Greek restaurant owner stipulated that his kidney should be used for a Greek national and at the same time Congress put on the books a law making it illegal to transplant foreign nationals.

What is our current practice? In the case of cadaver transplants after recipients have been medically screened for suitability, after all alternative forms of therapy have been explored (patients are already on Continuous Ambulatory Peritoneal Dialysis or Hemodialysis), informed consent for transplantation is then obtained. Following medical clearance the patient is placed on the computer list with SEOPF regardless of race, color, creed, sex or country of origin. Recipients are selected by the computer on the basis of HLA and DR matching in the absence of cytotoxic antibodies. When a kidney is either obtained or procured from local organ donation, or offered to us through the SEOPF computer, the list is first checked to see if the kidney would be compatible and desirable for a local American recipient. If it is, she or he is given preference. If the kidney is not usable for an American recipient on the list at that particular time, it is offered to the best recipient in line. Priorities on the waiting list are established by SEOPF and are also applied to non-immigrant, non-resident candidates. The use of foreign recipients decreases the distribution problem for cadaveric organs, increases the percentage which is actually used, enlarges transplant programs to make them more efficient, provides case material for clinical investigation and like living-related donors is highly cost-efficient in that it helps to share fixed costs of a transplantation program for the American taxpayer.

One of our more frequent countries of origin for foreign nationals is Greece. This has come about because of my own lifelong interest in Greek medicine, an association of several decades with the Greek Society of Nephrology, the fact that the only American trainee ever selected for a Chair of Medicine in Greece was in training with us at Georgetown at the time, and lastly because many of our local citizenry have deep roots in Greek culture. It is well known that we have a Greek Orthodox Cathedral in Washington next to our National Cathedral, four other major Greek Orthodox churches, and at least 65,000 ethnic Greeks living in the Washington area. The Philoptochos Society (women's philanthropy) of three Greek Orthodox churches in the Washington area have provided funds for living accomodations for Greek patients and their families while they await transplantation and while they are treated by dialysis. They also help to provide such amenities as translation services, transportation to and from dialysis units, cultural support, visits to ethnic Greek homes, etc. The family lives in housing which is provided free by the Philoptochos Society and the arrangement is very similar to an agreement which exists for children undergoing congenital heart surgery at the National Institutes of Health, who are supported by the Greek Orthodox church in Bethesda.

Every foreign national's name is placed on a SEOPF transplant list and he awaits transplantation with delays that are largely predictable by the ABO blood type. In our Greek program, after transplantation and recuperation the patient returns to Greece and the next potential recipient is nominated from our list and after final selection and approval is made, the patient is transported to Washington. Funds are provided by the individual insurance programs or fraternal institutions which operate health systems in Greece and it is my understanding that deficits are made up by the Greek government. In addition to those recipients, there have been over the years a few Greek recipients who have come as private individuals providing their own financing.

From time to time there have been other non-resident citizens entered into our transplant program. They have included both military and civilian citizens of a number of foreign countries. Seven different countries in 1982 and six different countries in 1983. We use the SEOPF organization and rules for the allocation of cadaver kidney transplants. We do have a widely disseminated statement of policy giving Americans priority if a suitable American recipient is available for a particular kidney. All individuals are billed actual charges regardless of race, creed, color, or country of origin. Undue pursuit of collection of charges is not our policy in the case of truly medical indigent. There are no disparities in charges related to race, creed, religion or country of origin. We are not aware that any individuals have been transplanted out of turn or moved up on the recipient list because of financial, political, or personal reasons. A very few patients have been given priority because of medical emergencies. The usual one is a rapid deterioration of clinical condition with prospects of imminent death. These medical criteria are applied regardless of race, creed, finances or country of origin.

Mr. Chairman, any legislation must be careful not to fracture the long standing ethical and legal traditions of our country. It is my firm belief that a rigid policy is not workable nor enforceable. If Congress so desires, our general philosophy could be incorporated into a guideline, namely that we should make our facilities available on a traditional American basis of compassion so long as adequate consideration is given to American recipients. The presence of non-Americans on the list, as we have mentioned, in fact increases the efficiency of distribution of organs and reduces the number of donated organs which are otherwise wasted or unused or unmatched. We must remember, that when an organ donor signs the Organ Donor Card or on the driver's license, he is in fact making a contract with society. We who work in this field have a very high moral and legal obligation to support whatever system promotes maximum utilization. He intended his organs to be used for transplantation. It is obviously defaulting in our obligation if we fail to use them. In addition, we must remember that the traditional compassion shown to relatives of the diverse ethnic groups who make up the American population has positive reinforcement and good repercussions within the related American groups of ethnic origin. Such a liberal policy enhances the volunteerism in organ donation. For example, the 65,000 ethnic Greeks in the Washington area have taken a much more profound interest in transplantation since the success of our cooperative program.

There are very few countries which have the medical manpower or the surplus transplant capability such as we have in the United States. Great Britain appeared to transplant non-resident aliens with great freedom and flexibility until their program was dealt a severe disservice by the broadcast media. After the BBC program criticising the British criteria for brain death, organ donation declined greatly and some British transplant programs ground to a halt, were forced to tighten up their selection process or delay non-resident alien recipients. A number of waiting lines existed for time periods which were untenable. In fact a few patients waiting for long periods of time were sent to the United States in a very advanced condition. I do not believe we should, nor have we sent organs outside of the United States when there is a United States citizen or a non-immigrant, non-resident patient in the United States who could medically accept the kidney.

Mr. Chairman, in general, I feel that it is extremely important to have a liberal and flexible program dealing with referrals of foreign non-immigrant patients. First of all, on a purely service basis, Washington's transplant capability can easily serve its indigenous population, its military requirements and the foreign nationals at a level at or above current practices. Secondly, the goodwill and political benefits of a compassionate policy are particularly visible and evident in our international community. The presence of foreign Embassies in Washington for support services renders it the natural place for such transplants to be centered. Washington is, after all, the International Capital of the world. Maintaining a large recipient list increases the efficiency of distribution and renders a higher percentage of donated organs to be useful and actually used. It also facilitates research in clinical investigation. As long as no American recipient is being denied a kidney by the current methodology, the benefits of continuing our current practices far outweigh the theoretical benefits of a more restrictive policy. In fact, the larger programs which are made possible by such practices actually help to share the fixed costs of transplantation programs and the research activities for the hospital, the university and the United States taxpayer.

Respectfully submitted,

George E. Schreiner

George E. Schreiner, MD
Professor of Medicine
Director, Nephrology Division
Georgetown University School of Medicine

Mr. GORE. Thank you very much. I appreciate it.

I have a number of questions. First of all, Dr. Light, you just came to the Washington Hospital Center from Walter Reed, is that correct?

Dr. LIGHT. Yes, sir, that's correct.

Mr. GORE. Now, you've given us some figures. We got figures earlier from the Health Care Financing Administration. Yours seem to be different. I will ask the staff to explore that with you outside of this hearing. But for these purposes, let's use your figures.

In 1983, you have done 35 transplants, correct?

Dr. LIGHT. Yeah, that was through October 9.

Mr. GORE. Through October 9. And 15 of the 35 have gone to nonimmigrant aliens, is that correct?

Dr. LIGHT. Yes, all Saudis.

Mr. GORE. Pardon me?

Dr. LIGHT. They were all Saudis.

Mr. GORE. They were all Saudis.

That seems like such a high percentage. Can you just tell me briefly why 15 out of 35 transplants you did would go to Saudis?

Dr. LIGHT. It wasn't me.

Mr. GORE. The Hospital Center.

Dr. LIGHT. No, I really don't know the specific instances. I think when trying to delve into these things you find that the patients were getting a service in a relatively timely fashion, it was succeeding relatively regularly, and I suspect that that was the mechanism by which it all occurred. There was no—I couldn't uncover any financial incentives or any other kind of special incentives to either physician or the hospital.

Mr. GORE. What do you charge for a transplant?

Dr. LIGHT. I can honestly say that I don't know what the figure is. I've been in the fee-for-service thing for such a short time that I don't really and truly appreciate that.

Mr. GORE. You looked at six random sample cases, did you not?

Dr. LIGHT. Yes. These were the total hospital bills to include physician charges, as I understand it.

Mr. GORE. And what was the average in those six random cases?

Dr. LIGHT. $49,000 for the Saudis and $51,000 for the Americans.

Mr. GORE. $49,000 for the Saudis and $51,000 for the Americans; that's the total transplant?

Dr. LIGHT. That was the total hospitalization cost for the—I presume it was the duration of the first stay. I didn't, you now, include rehospitalizations or, you know, things later on in the year. But this was the standard figure for the duration of the stay after the transplant.

I believe it included donor cost as well as surgeon's cost, although I can't absolutely swear to that.

Mr. GORE. What were the actual payments in the cases?

Dr. LIGHT. That I don't have any information for. I understand that the bills are referred to the Saudi health office and that reimbursement is taken directly from that.

Mr. GORE. What were——

Dr. LIGHT. I think all our traditional recipients are eligible for whatever the standard reimbursement is, which I assumed was—

which I was given to understand was 100 percent of the initial transplant cost.

Mr. GORE. Well, these are charges. Do you know what—You don't know what the actual payments were from the American citizens?

Dr. LIGHT. No, sir, I don't know. But I do know these were medicare recipients.

Mr. GORE. Well, let me give you an example. What was the surgeon's fee, do you know?

Dr. LIGHT. That I don't know, sir.

Mr. GORE. If you could supply that for the record, I would appreciate it.

[At the time of printing, the material was not received.]

At George Washington, Dr. Karmi, what is the surgeon's fee?

Dr. KARMI. It's $6,000.

Mr. GORE. $6,000. And that's comparable to the $2,000 that Dr. Feduska mentioned in California——

Dr. KARMI. I think so.

Mr. GORE [continuing]. In his institution.

Now, of that $6,000, medicare reimburses $3,800; is that correct?

Dr. KARMI. $3,800, or $3,900.

Mr. GORE. Or 80 percent of $3,800. So presumably—well, the patient would have to make up the difference, is that correct?

Dr. KARMI. That's right—not the medicare patient.

Mr. GORE. The medicare patients, that's all you——

Dr. KARMI. No, they are all charged the same way, through this list, and this list is made through——

Mr. GORE. But medicare patients don't pay the difference?

Dr. KARMI. They don't pay the difference.

Mr. GORE. They don't. So with the medicare patient you would get paid $3,800——

Dr. KARMI. Yes, sir.

Mr. GORE [continuing]. And for a nonmedicare patient, you would get paid $6,000?

Dr. KARMI. Not me. The university, sir.

Mr. GORE. The university would.

Dr. KARMI. Yes, sir.

Mr. GORE. The university hospital would.

Do you know of comparable data to that offered by Dr. Light about the difference in charges between American patients and nonresident aliens overall?

Dr. KARMI. No, sir. The only thing is that when these patients come to us, we send them to the business office, and they are given in detail the financial statement, which I have in my testimony. They do have to pay in advance because the university had suffered quite a bit from bad debts and allowances from these foreign nationals.

A lot of these, the ones that came, were on their own, actually.

Mr. GORE. Dr. Light, the figures that you have given to the subcommittee include a calculation of the average waiting time. For the medicare patients the average waiting time for a transplant has been 36 weeks, and for the average nonimmigrant alien it has been 12 weeks.

Could you explain why that would be the case?

Dr. **LIGHT**. Maybe I could first go back to the surgeon's costs?

Mr. **GORE**. Yes. I don't want to leave that prematurely. Yes, go back to the surgeon's cost.

Dr. **LIGHT**. I was just given to understand that that's $3,500 for all patients.

Mr. **GORE**. At your hospital it's $3,500 for all patients——

Dr. **LIGHT**. Yes.

Mr. **GORE**. Well, let's get Georgetown on the record on this as well. Do you happen to know, Doctor, either one of you?

Dr. **SCHREINER**. We have—our arrangement is we have a nephrology division, which is a section of the Department of Medicine, and we have a transplant division, which is a section of the Department of Surgery. Our standard workup fee for bringing the patient in, discussing all of the modalities—you must remember that not every patient who comes into the final thing is necessarily suitable or necessarily goes on to transplantation, but they need to have a total workup. With that in mind, if that is their election as the mode of substitution therapy for end-stage renal disease, in 1982 we charged $600 for that and in 1983 we charged $700 for that.

That, of course, has nothing to do with the surgical fee or the hospitalization fee. That money then goes into a practice plan in the Department of Medicine and is used to support research and faculty salaries.

Mr. **GORE**. What's the surgeon's fee?

Dr. **SCHREINER**. I don't know.

Dr. **HELFRICH**. Around $3,750, and I should point out there is no differential between hospital charges, or lab, or blood products, or beds, or anything, between a foreign national and an American citizen. And the collection rate at Georgetown for foreign nationals is less than it is for U.S. citzens.

Mr. **GORE**. I see. OK, very good.

I guess that raises a question. We have heard from four hospitals, one $2,000, one $3,500, one $3,700. I guess this is kind of off the point, but why is yours $6,000?

Dr. **KARMI**. Well, it's the business office that decides certain—most of the hospitalization, and the Departments of Surgery decide on their fees. If you think about it, compared to other surgical fees that you have, with even cardiac surgery, which takes a patient ten days to recover, and his surgeon does not see him any more, while you spend 3 months with this patient, spending all this time, it comes out to be $10 an hour, which is much less than a plumber or the——

Mr. **GORE**. Well, as I say, it's a little bit off our main point, but I guess we could be grateful that these other centers didn't think about it as long as you all thought about it.

Now, let me come back, Dr. Light, to my first question to you, because I don't think yet that I fully understand why you have such a high percentage.

Dr. **LIGHT**. I can clarify the column and—I understand your question, I think.

Mr. **GORE**. Fifty percent, almost 50 percent, is extremely high, it seems to me. Last year it was 40 percent. Why would it be that high?

Dr. LIGHT. You know, I wasn't there. I don't know the specifics of that, and I really don't think——

Mr. GORE. You conducted an investigation of this very question at our request, right?

Dr. LIGHT. Uh-huh. I could provide you with data. Do you want me to——

Mr. GORE. Well, I would like to know your conclusions as to why this is the case.

Dr. LIGHT. OK. There is an active referral situation. I don't know of any incentives for that. But the patients do come to the hospital center via the Saudi health office, and there's an individual referral practice between my predecessor and the nephrologist physicians at the Saudi health office.

If we look—you know, I think——

Mr. GORE. Now, wait a minute. Does your—does he—do most of these cases come from that doctor?

Dr. LIGHT. There are two physicians associated with the Saudi health office.

Mr. GORE. Do they have a contract with the Saudi Government?

Dr. LIGHT. No, there's no contract that I know of.

Mr. GORE. But they have a professional association with—they have an association with the Saudi health office established here by the Saudi Embassy, right?

Dr. LIGHT. I don't think I can draw conclusions. It's outside the realm of what I know and what I was able to find out.

Mr. GORE. Two doctors refer all the cases to you, right?

Dr. LIGHT. To—yes, to the hospital.

Mr. GORE. OK. One of them was your predecessor?

Dr. LIGHT. No, I think maybe the implication is incorrect. The transplant program at the Washington Hospital Center received referrals from two physicians associated with the Saudi health office.

Mr. GORE. Are they Saudis or Americans, the referring physicians?

Dr. LIGHT. The referring physicians I believe are Saudi, but I don't know either one of them individually.

Mr. GORE. OK. Well, go ahead and tell me why 50 percent, almost 50 percent of your transplants are going to Saudi Arabians.

Dr. LIGHT. I still think it's hard to come up with an answer that you're really going to be able to really get your teeth into, if you will. It's still, it's a group of patients who need health care. The service is being provided at a reasonable cost in terms of comparable places in the country. They seem to get their transplants efficiently and the outcomes are satisfactory. I think—you know, it's like a lot of other things. It appears that success sort of breeds continuing referral. How many of the patients came directly from recommendations of other patients versus via their government, I don't know.

Mr. GORE. Now, where do most of the kidneys used in these transplants come from?

Dr. LIGHT. If you look at the sheet entitled "Donor Allocation," which is a recent addition to your information——

Mr. GORE. Yes.

Dr. LIGHT [continuing]. There you'll see under source——

Mr. GORE. Yes.

Dr. Light [continuing]. And when you look at it percentage-wise, it turns out that a smaller percentage of the NRA kidneys, the nonresident aliens, or Saudis, in general, that a smaller percentage of them, 26 percent, come from local kidneys, versus 31 percent for our standard beneficiary population.

Most of the kidneys, in fact, came from the computer selection. It's hard to explain that, except that perhaps, since we use DR matching as the primary selection device in the last year-and-a-half, that they have more common DR antigens associated with our donor population.

Mr. Gore. Has Washington Hospital Center received any grants from the Saudi Arabian Government?

Dr. Light. No, sir.

Mr. Gore. From individual Saudi Arabians?

Dr. Light. Not to my knowledge, and not to the knowledge of any of those associated with the financial structure of the hospital.

Mr. Gore. All right.

Now, in preparation for this hearing, and at the specific request of the subcommittee staff, you and others analyzed the data for nonresident transplants in patient—in terms of patient selection and financial incentives; you have already acknowledged that. And charts were prepared as well.

Can we have that information?

Dr. Light. Yes, sir.

Mr. Gore. Do you have it with you?

Dr. Light. I have given it to Mr. Nicholas.

Mr. Gore. We have been given a composite of the information. Could we get the background data?

Dr. Light. I have individual bits of data which are blinded for names. I don't have any——

Mr. Gore. Could we look at that?

Dr. Light. Yes, sir.

Mr. Gore. All right, good.

Now, have any nonimmigrant aliens been given preference over American patients for kidney allocation at your institution?

Dr. Light. I think, again, it's very hard for me to say. Looking at the data alone—and if you'll please accept that, there are a wide variety of things going to recipient selection, as you have heard from a number of different people. So I don't know the details of why certain things were done or how they were selected.

But there do appear to be cases where nonresident aliens received local kidneys when there were better nonlocal matches available. When we review the computer list, we can find in the region and in the country other patients who had better matches than were those used locally. What the other confounding variables are can't be addressed. They're not in black and white anywhere.

Mr. Gore. OK. Well, I appreciate your candor. It's very helpful.

Now, what about on your own waiting list within the Washington Hospital Center; have nonimmigrant aliens been given preference over American citizens on the waiting list with an acceptable match?

Dr. Light. I don't have a waiting list—I mean, I just went there and I don't have any nonresident aliens on the list. They will probably——

Mr. GORE. No, no. I'm talking about as a result of your review which you and others did at your center at the request of the subcommittee. Did you find instances where nonimmigrant aliens were given preference at the center over American citizens that had an acceptable match?

Dr. LIGHT. That did not occur as far as we could decipher on any of the kidneys that came from computer selection that were imported into the center. As I mentioned a moment ago——

Mr. GORE. Well, before you get away from that answer, let me ask you to address the rest of the universe of kidneys that the question focused on. Let me ask you more precisely, did you find any cases where a nonimmigrant alien was given preference over an American citizen with an acceptable match within your center, for kidneys harvested at your center?

Dr. LIGHT. I could not find evidence of that, and I specifically asked a number of people because of concern about that issue. We could not find a specific instance, even looking through each record and each recipient on the waiting list, the disposition of every donor kidney in the last three years.

Mr. GORE. Well, now, we heard a statement earlier—You see, this is one reason why we want to see this back-up information. Could we look at that?

Dr. LIGHT. You can have everything I brought.

Mr. GORE. We heard testimony earlier that a patient at your center was called during the summer and told that kidneys were going to be imminently available at the center, and to stay near the telephone. The patient, according to the story, was never called and then found later that both available kidneys were transplanted instead into two nonimmigrant aliens at Washington Hospital Center. The patient did not wish to testify, but we talked with others who gave us reason to believe that this was, in fact, the case.

Dr. LIGHT. I understand.

Mr. GORE. Are you familiar with that particular case?

Dr. LIGHT. No; not specifically, but if you can tell me the date, I can find it.

Mr. GORE. It was in July.

Dr. LIGHT. In July there were——

Mr. GORE. We believe it was July, perhaps early August.

Dr. LIGHT. Well, there were a number of transplants performed in that specific time.

Mr. GORE. We asked you specifically to look at this case, right?

Dr. LIGHT. No, I wasn't specifically asked to look at that case, not in the material I received in writing. I'm not trying to avoid the situation——

Mr. GORE. Were you asked orally?

Dr. LIGHT. I honestly don't think so.

Mr. GORE. OK.

Dr. LIGHT. We—I reviewed, while we were listening to testimony earlier, with the two coordinators who were on duty at that time, or who were employed with the center at that time. They can't recollect any circumstance analogous to the one you present. The best I can do is look back through the record which occurs at about that timeframe and try to make some judgment about whether that might have occurred, because there is no list anywhere in the files that says a certain number of patients were contacted or how this was done and so on. All we have is the specific information on——

Mr. GORE. OK. We'll come back to that when we've had a chance to review this data.

Now, what about the waiting list? The composite information that you did supply to us indicates that nonimmigrant aliens have a waiting time one-third that of American citizens. Why would their transplants come that much faster?

Dr. LIGHT. There are two or three reasons. Again, in analyzing all the features, the specific figures are that our medicare recipients wait 41 weeks on the average, with the O blood group waiting slightly longer than the A, as you heard earlier, and the nonresident aliens have a mean waiting time of 16 weeks, slightly longer for the O's and less long for the A's.

They are a more favorable group to find a kidney for, in the sense that almost all of them are first transplants. Few of them are sensitized, so that the cross matches are generally negative and you can accept, if you will, a lesser match.

I think, in part, some of the information is confounded by the upcoming availability of cyclosporin, and I think that in the month and a half or so when I was involved with organ allocation and recipient selection, it appeared that in many circumstances there was preference to allowing the Americans to wait unless there was an excellent match, hoping for a better drug and a better outcome for them, especially if they were already second transplants or if they had previously or were highly sensitized. So I think there was not a conscious, necessary—necessarily a conscious mechanism. I think in part it was related to the hope that we would do better if some other factors thought to except——

Mr. GORE. Well, you have excluded the highly sensitized patients from the figures here. In fact, the discrepancy would be significantly larger if you included the sensitized patients in the numbers.

Dr. LIGHT. Let me clarify two things, OK.

The first column under waiting time refers to those who have been transplanted already. The second part refers to those who are still remaining on the list.

Mr. GORE. Yeah.

Dr. LIGHT. And the ones who have not yet been transplanted are presently waiting 12 weeks, for example, for the Saudis, and 36 weeks for the medicare beneficiaries. I excluded the five who were sensitized greater than 90 percent, and as you see in the footnote there, their waiting time is so long as to make the mean unrevealing.

Mr. GORE. Yes, OK.

Now, the reason why Americans have to wait three times longer at your center is that the nonimmigrant aliens are usually easier to transplant; is that what you said?

Dr. LIGHT. Well, let me repeat myself on that and say again that they're an easier group primarily because they are not sensitized, so that means there'll be no possibility that there'll be a positive cross-match, for example. Few of them are sensitized, 22 percent versus 48 percent, for example.

Mr. GORE. Now, when you say "sensitized," you mean—what you're talking about there is someone who has had a blood transfusion or——

Dr. LIGHT. A clarification, it's the same word as immunized or the same one that says they've had antibody——

Mr. GORE. They've had some kind of experience in their prior history which has led to an increased number of antibodies which, in turn, decrease the chances of a successful transplant?

Dr. LIGHT. Right.

Mr. GORE. Is that what you're saying?

Dr. LIGHT. Uh-huh. So, you know, if you bear in mind that most of the—most of our kidneys came what I thought was inextricably from nonlocal sources, they came from the computer, somebody else selected—that they send the kidney here—when you try to look at why would somebody send us that kidney when they could have sent it to Indiana, Illinois, or wherever, one of the reasons is that the sending institution would like to see that kidney used. That's part of it. The second part is that in any given center, if there are two or three patients who are eligible, in case one is sick or some other problem comes up, or the cross-match turns positive, you can still use that kidney. Whereas recycling it, transporting it to another center and so on, may exceed its acceptable lifetime.

Mr. GORE. OK. Now, but, you testified a moment ago that your review indicates that, in fact, nonimmigrant aliens at Washington Hospital Center have been given kidneys that were an acceptable match for American citizens outside of Washington Hospital Center?

Dr. LIGHT. There was no policy at the time——

Mr. GORE. There was no policy. Is there a policy now?

Dr. LIGHT. There is one pending, which I have recommended.

Mr. GORE. Tell me what policy you have recommended.

Dr. LIGHT. Recommended that we give first priority to our beneficiaries, our citizens.

Mr. GORE. Your what?

Dr. LIGHT. To the citizens of the country.

Mr. GORE. To American citizens?

Dr. LIGHT. I mean, whatever—you know, I guess they're American now. I mean, not everyone comes from America that's an American citizen.

Mr. GORE. Right.

Dr. LIGHT. So our beneficiary population, however we define that, as being our resident group—maybe that's a better term than our citizen group—but people who pay taxes and live here and so forth. That's in the testimony.

Mr. GORE. Would a nonimmigrant alien under this policy still be given preference over an American citizen at Washington Hospital Center versus Georgetown Hospital?

Dr. LIGHT. We intend to have made a reasonable search, and that reasonable search would include all possibilities of local, regional, or national sharing prior to considering the waiting group of nonresident aliens.

Mr. GORE. And that policy is now pending. OK.

Dr. LIGHT. That policy is not in effect. That policy is recommended.

Mr. GORE. It is a policy that you have recommended and the hospital board has to vote on that; is that right?

Dr. LIGHT. They're voting on it and referring the issue to the ethics committee.

Mr. GORE. Have you—After beginning consideration of this new policy, did you transfer any nonimmigrant alien patients to other medical centers?

Dr. LIGHT. None of those patients are mine, OK, and——

Mr. GORE. Did the——

Dr. LIGHT. Let me continue, please.

Mr. GORE. Yes.

Dr. LIGHT. None have been transferred, to my knowledge.

Mr. GORE. All right. OK, fine. All right.

Dr. Helfrich, for the period—again, the figures are a little bit different from HCFA and from your own testimony. Using your own figures, this year 33⅓ percent of your transplant patients were nonimmigrant aliens; is that correct?

Dr. HELFRICH. Yes, that's correct. But if you were to examine the data a bit stronger, 14 of our cases were living relateds, so about 50 percent of what we have done this year, 15 of 33, would be nonimmigrant aliens.

Mr. GORE. So when you look just at cadaveric transplants—which is really the correct way to analyze this issue—50 percent of your patients also are nonimmigrant aliens.

Let me ask the same question. Why?

Dr. HELFRICH. The response that I would give is that we have been selected by, so far this year, six different foreign countries to perform transplant procedures on their patients. The stated policy that we have is they will not receive consideration for transplant—and this has to be ethically put to them before they enter our program—that they cannot receive a kidney that would otherwise go to any U.S. citizen anywhere, Hawaii included.

Mr. GORE. Now, is that for—does that policy apply to kidneys harvested at your institution?

Dr. HELFRICH. It applies to any kidney that would be transplanted to any foreign recipient in Georgetown. In other words, we may accept a kidney for another patient. That other patient may be sick, may have a positive cross-match, may not want it—occasionally that occurs. And then we try to place that kidney anywhere in the remaining United States, bearing in mind that there is a time limit on how much you can get accomplished before the kidney is no longer useable. And we reach the time limit and no one else wants it, the foreign nationals get it.

We also ask the kidney center in Richmond to consider sending kidneys to Georgetown prior to sending them overseas. Now, this is an important area because it utilizes an American resource here in America rather than sending it across the ocean. I think as long as the foreign nationals do receive consideration for a resource that would otherwise be discarded, the tissue would be discarded, then that's a utilization of a kidney that otherwise would not have been used.

Mr. GORE. All right.

Dr. HELFRICH. If my daughter dies and they can use it in a foreign national, I would much rather have it used than not used.

Mr. **Gore**. Than not to be used at all.

Dr. **Helfrich**. That's the bottom line. I would rather have it used.

Mr. **Gore**. Absolutely.

Now, if you harvest a kidney within your own hospital, the same policy applies?

Dr. **Helfrich**. Absolutely.

Mr. **Gore**. So if you harvest a kidney within your own hospital and there is an American citizen in Kansas that can use it, that American citizen in Kansas will get preference over a nonimmigrant alien in your hospital?

Dr. **Helfrich**. Yes. It's important also to realize, when you made your comments earlier about regionalization, southern California, Illinois, and so on, for purposes of getting an optimum result, if you have an equal match in Washington and an equal match even in Richmond, or in New York or Chicago, or further away, you try to place the kidney with the best match that's closest so that the injury from cold preservation doesn't interfere with the eventual function.

Mr. **Gore**. I understand.

Dr. **Light**. Could I mention one other thing with regard to that?

Mr. **Gore**. Yes.

Dr. **Light**. It's an augmenting point, basically, and that is that there is, as you already appreciate, incredible public relations value from and feedback information to the donor hospital. Nothing is better in terms of promoting organ procurement within an institution than demonstrating that a patient they know or know about in the community gets that resource rather than someone in Iowa.

Mr. **Gore**. Yeah. Well, I agree with that policy, but do you have dissenting opinions in your hospital?

Dr. **Helfrich**. I'm simply the director of the transplant division. The hospital and the institution have a different position, and I think your earlier comments bear particularly upon my own personal circumstance.

I'm a physician so I deal in medical ethics, and I think it is medically questionable that you make a decision to transplant a kidney into somebody on reasons other than medical indications. So I strongly feel this way.

However, the institution and the citizen responsibility to Americans and so on made it clear to me—and I think I discussed this with Dr McDonald before we made a policy—that we had to protect the institution from any future situation in which it may become apparent that a foreign national was given any kind of preference.

Mr. **Gore**. So it's a political decision.

Dr. **Helfrich**. It is a pragmatic decision. When you say political, my response is that it's political only in the sense of protecting the institution from future criticism.

Mr. **Gore**. Yeah, I mean the word political in a generic sense.

Dr. Helfrich, do you agree or disagree with this policy? Dr. Schreiner, I'm sorry. It's been a long hearing.

Dr. **Schreiner**. Naturally I feel very strongly that the more—at least in Washington—the more foreign transplants that we could do, the better off we would be politically for our country and also in terms of good will. As with everything else, when you're in the real world you have to counterbalance what is desirable against what is going to be viewed or perceived by the people who are perceiving it.

I can also see that the American citizen has some justice on his side because were it not for the setting up of end-stage renal disease under the medicare law, first, we would have much fewer transplant units and a lesser transplant capability in the country, and second, much of the apparatus that is in place is in response to the critical mass that was provided by covering our individuals under medicare.

One could see that there were a total—in 1972 there were a total of 5,000 people cared for in the whole United States that we know about, and now we're up with thousands of transplants, something very close to 100,000 people, and in the word, some 200,000 people. So that it is quite obvious that medicare has provided the single major sinew for the expansion of the structure, if you will. If you look at the apparatus that provides this medical care, it did exist in a small number of selected centers, but it certainly wasn't as widespread as after medicare. So I think the American citizen has a certain amount of justice on his side when he feels that as a result of providing that structure, if you will, and the sinews by which it works, that he should be possibly not moved out of the queue, if you will, in some way that he doesn't understand by persons who may have more financial resources or what have you. So I can see justice on both sides.

We feel that what we have tried to do is to walk the tightrope in the most reasonable possible manner, and I think in the real world I would certainly approve of that. I think it may not be ideal when you look at the foreign person, from his viewpoint; it may not be ideal when you look at the American person from his viewpoint. But it is a policy which realistically does the best for both people.

Mr. GORE. So that's a yes, you do reluctantly agree with the policy.

Dr. SCHREINER. No, I wouldn't say reluctantly. I would say it's a realistic policy in the real world.

Mr. GORE. And you do agree with it.

OK. I want to come back to a couple of other questions, but Dr. Karmi, your policy at—first of all, according to your figures, you have what, 22 percent of your transplants go to nonimmigrant aliens this year? No, that's in 1982.

Dr. KARMI. In 1983 we have 1 foreign national out of 16.

Mr. GORE. I see. And that's as of what date?

Dr. KARMI. As of January 1983, to this October.

Mr. GORE. I see.

Dr. KARMI. We had 16 transplants and one Turkish lady got the——

Mr. GORE. The 22 percent was last year, in 1982.

Do you agree that American citizens ought to be given a priority or not?

Dr. KARMI. I don't know. I feel, from the point of view of being a physican, and a physican has to treat patients with the best way that he can, and the best way of treating end-stage renal disease is a kidney transplant. I cannot segregate patients according to national origin or sex or race, and I hope we don't get back to the period when—I think Dr. Schreiner remembers that—that when people were fussy about who gets the kidney, whether he's a black or a Chinese or who wants to give a kidney to a black or a white.

So in medicine I think we cannot differentiate, at least that's my feeling. I checked with the vice president of the university and others, and they say this is our policy——

Mr. GORE. That is your—in other words, your hospital's policy is not to give a preference to American citzens, but——

Dr. KARMI. No.

Mr. GORE. That's the policy?

Dr. KARMI. That's the policy, quoting the vice president, that all patients are equal.

Mr. GORE. Now, Dr. Schreiner, at your hospital at Georgetown, the division of nephrology sort of has control over the program that includes both dialysis and transplant. Transplant is considered a point on the continuum of treatment for kidney patients; is that correct?

Dr. SCHREINER. We have a number of services within the nephrology division, and one of them, of course, is a clinical diagnostic service. Very often——

Mr. GORE. OK. I don't want to go into all of that. I just wanted a basic understanding of the fact that, unlike in some other hospitals, at your hospital the division of nephrology is basically in control of things.

Dr. SCHREINER. Well, I don't think that we are to a degree that we are in control of the surgical aspects of transplantation. What we have is a cooperative med-surgical unit in transplantation, but in nephrology the workups are done originally, as the patients are brought in, worked up and the various alternatives are presented to them. Because we feel that the patient should be presented all of the alternatives.

Mr. GORE. OK. All patients are first referred to nephrologists.

Dr. SCHREINER. In general.

Mr. GORE. All right.

Now, does the division of nephrology have any formal or informal agreements with foreign governments?

Dr. SCHREINER. We have a formal agreement with the Greek Ministry of Health, yes, sir.

Mr. GORE. And what is the nature of that agreement?

Dr. SCHREINER. This was negotiated—I might point out with pride that the first nephrologist, or the first person, the first physician in the history of the Greek Government to be appointed to a chair of medicine while outside of the country was one of our fellows, and he became chairman of medicine at the first service in Thessalonica. I have had very close personal ties with the Greek Society of Nephrology and, indeed, during my tour as president of the International Society of Nephrology we held our International Congress in Athens. I visited there many, many times.

So as a result of these, we were approached by the Ministry of Health to see whether something could be done about their problem. They had 123 people on a waiting list waiting for transplantation, and a transplant capability which had no possibility of catching up with it. We asked them to put their views in writing. They did. And we countered with our views and including our policy of our institution, which they obviously didn't like, that we do not give any nonimmigrant national a kidney that can be used by an American.

And this agreement was subsequently approved through channels at Georgetown. And at that point they had an election, if you'll recall, and a new government took over, so it was suspended for about a year. The new Minister of Health who succeeded Professor Doxiades, on his own, requested that we renew the negotiations.

Mr. GORE. OK. What's the nature of the agreement?

Dr. SCHREINER. Simply that they will send the patient over here—the way the mechanics work is, they send us résumés of patients to ask whether they would be suitable to be placed on the list, and we answer yes or no. Then the Ministry of Health makes the decision, although we tell them, you know, what the realities are in terms of typing and so forth, they make the decision for sending the patient. The patient comes here and he stays here in facilities that are provided by the philoptic societies of the Greek Orthodox Churches of Washington and he stays on dialysis until a suitable kidney becomes available. He is not given any preferences and he may wait a very long time, if he is a type O particularly.

Mr. GORE. Does the arrangement include financial arrangements?

Dr. SCHREINER. They simply pay the bills, yes.

Mr. GORE. And they are charged at the same rate as medicare patients?

Dr. SCHREINER. Yes, sir.

Mr. GORE. Now, has your hospital gotten any grants from the Greek Government?

Dr. SCHREINER. No, sir. It is also limited to one patient at a time. In other words, they don't send the next patient over until the previous one is returned. So it's not a flood. And I think this has produced some very excellent things. If you may permit me, I just happen to get this morning a postcard from them, from patient so and so. [Handing to Chairman Gore.]

Mr. GORE. That's very nice. It's in English, also. Yeah, that's very nice.

Dr. SCHREINER. By the way, he didn't speak very much English when he came here, but he did when he left, because he waited for a very long time.

Mr. GORE. I see. I see. All right.

Now, it's your testimony, and yours, Dr. Helfrich, that no nephrologists or surgeons associated with Georgetown benefit financially, directly or indirectly, to a greater degree if an NIA is transplanted instead of an American citizen; is that correct?

Dr. Schreiner——

Dr. SCHREINER. I'm sorry, I didn't——

Mr. GORE. That you and the hospital benefit the same whether it's an NIA or, a nonimmigrant alien or an American citizen?

Dr. SCHREINER. Well, with the delay in reimbursement from our new medicare intermediary, I suppose you could say we get less from the medicare patient.

Mr. GORE. I see. OK. That's a candid answer.

Now, Dr. Schreiner, we heard testimony earlier that was very, very troubling. There was no nephrologist in the room at the time and now you're here and I've got to ask you.

The testimony was that only 10 percent of the patients on dialysis are currently on the transplant waiting lists, and most doctors, according to the statement we heard earlier, believe that that figure should be 30 percent instead of 10 percent. There was an implication in the statement earlier that some nephrologists are reluctant to turn over control of their patients to surgeons—maybe they don't have the kind of working relationship that you have between nephrology and surgery at your hospital—and that as a result many thousands of patients who could benefit from a transplant and ought to be on a waiting list are not aware of it and are not put on the waiting list.

I would like you to respond to that, if you could.

Dr. SCHREINER. Yes, sir. I think it's a very, very important question and can be a very troublesome one. Let me just make a whole series of brief facts, first of all.

Obviously, there are places in the United States which only offer one particular modality of treatment. That may be by choice or it may be by resource limitation. It is obviously more likely, in a community that has only one modality of treatment, to prefer that particular modality of treatment, simply because it's the most familiar to them and the one that they're used to recommending, and I think that's what you would call local standard of practice. Obviously, if you're in a city and there is no transplant unit in the city, then you're thinking dialysis; all of the time.

The same thing takes place with respect to modalities with inside, within dialysis; that is, whether you use CAPD, for example, or CCPD, or IPD, or whether you use hemodialysis, whether you use storefront dialysis, self-care, and so forth, each one has its advocates and each one is apt to give you rhetoric suggesting that their particular mode of therapy is better in their hands than anyone else, which is part of the pride and ego of being a physician, I guess. And to some extent there is a little bit of personal justification for that.

The possibility, of course, always has to exist—and that's, I'm sure, one of your oversight functions—to make sure there are not ulterior motives. We would, as one who was instrumental in getting this legislation, I feel very, very strongly that that ghost should never be allowed to raise its head, that there should never be any ulterior motive for selecting one particular form of therapy. So——

Mr. GORE. Well, do you think it is a problem now; there are a lot of them who are on dialysis who should be on the waiting list and aren't?

Dr. SCHREINER. Well, if I ever hear about it, I certainly will use all of my influence and the influence of the societies to which I belong to stop it, because nothing would be more detrimental to the program.

Mr. GORE. OK. Well——

Dr. SCHREINER. We feel very strongly that every patient should be exposed to the pros and cons in an objective fashion to every form of therapy, and not be approached by somebody who is either a proponent or an adversary or doesn't have an open mind.

Mr. **Gore**. OK. Well, we will pursue that at another time. The subcommittee will pursue that at another time. I hope you will consider yourself as having heard about it this morning, that the number on the transplant list probably ought to be tripled.

Dr. **Schreiner**. I'm not sure that I would accept that. For one thing, in recent years, at least in the Washington area, there has been a disproportionate addition of elderly diabetics on to the dialysis rolls, and that——

Mr. **Gore**. We excluded those in the earlier—we excluded elderly patients earlier, in the earlier interchange.

We can talk about this further. Our hearing is not focused on that specific subject, but it did come up and, as a nephrologist, I felt you ought to be asked about it and have a chance to comment.

Let me just ask two more questions. It's been a very long hearing and I appreciate your patience.

Dr. Karmi, you were quoted in the *Washington Post* as saying that nonimmigrant aliens pay double for transplants, and as a result, hospitals make a lot of money from procedures on nonimmigrant aliens.

Do you—is that correct?

Dr. **Karmi**. No, sir, I was misquoted in that thing, not quoted, which I may say so. The thing is, when I was asked on the phone to comment on foreigners, getting patients and getting preference, getting transplants and getting preference because of their financial ability, I said no. The hospitals want to get their money back. Nobody wants to be in the red. And these patients pay their money in full and in advance. We have a lot of problems—talking about the $6,000 and things, four of these patients we did we never collected any money from. The hospital, unless he gets the money in advance, we will not be able to admit the patient. No matter how we beg the business office, there is no way the patient could be admitted.

And the patients—and the administration is happy that it pays its costs, it covers its costs, instead of what it gets reimbursed from medicare, which doesn't cover the expenses and the costs.

Mr. **Gore**. OK. Well, let me say—excuse me. Dr. Helfrich.

Dr. **Helfrich**. Excuse me. Pertinent to the same article, I believe Mary Batiatta wrote it. We were misquoted also, and I think the article was a disservice to people. It stated in there that we would make exceptions for foreign nationals, and both the physician who was misquoted as saying that, and my own furor upon arriving back at the university that anyone would say such a thing, has satisfied me that her intent was to stimulate some interest.

Also, she did interview Dr. Schreiner in detail and he was not mentioned at all in the article. I don't understand what that article was intended to do, but it certainly was full of misinformation.

Mr. **Gore**. Well——

Dr. **Schreiner**. I spent more than an hour with her and she never used a single thing that I gave her.

Mr. **Gore**. Well, I have certainly had that experience. And as a former reporter, I have had the experience on the other side of the note pad also years ago.

Anyway, let me say that I think we have learned a lot during this hearing today. I know I have learned a lot. I hope that it has been helpful. We are going to review the additional material submitted for the record. We will have further questions in writing, not a large number of them, if you all would be willing to respond to some additional questions. And we may have recommendations.

It does seem to me that the country as a whole is moving on the whole transplant issue. Medical centers around the country and procurement networks and citizens of the country are becoming more aware of what tremendous opportunities there are to save lives. And as more transplants are performed, and as the awareness increases, some of these difficult questions about how to assign priority to patients will receive a great deal more attention. And that's good. It is my hope that this hearing will be a positive influence in trying to stimulate a more rapid adaptation to the new bioethical imperatives that the increased number of procedures carry with them.

I would like to thank the members of this panel. I would like to thank all of the witnesses that have appeared today for a most helpful and illuminating hearing for me. I appreciate it very much.

With that, the hearing will stand adjourned.

[Whereupon, at 2:20 p.m., the subcommittee was adjourned.]

PROCUREMENT AND ALLOCATION OF HUMAN ORGANS FOR TRANSPLANTATION

WEDNESDAY, NOVEMBER 9, 1983

House of Representatives,
Committee on Science and Technology,
Subcommittee on Investigations and Oversight,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:10 a.m., in room 2325, Rayburn House Office Building, Hon. Albert Gore, Jr. (chairman of the subcommittee) presiding.

Mr. Gore. The subcommittee will come to order.

I'd like to welcome all of our witnesses and guests.

Today marks the second day of hearings this week by the Subcommittee on Investigations and Oversight on issues related to human organ transplants. This is also the sixth hearing held by the subcommittee on organ transplants.

This morning the subcommittee will examine what I believe to be a question with enormous practical and ethical implications for our society; namely, the buying and selling of human organs.

Throughout this year, we have been engaged in an evaluation of our Nation's system for organ transplantation. Through the course of our inquiry we have learned that thanks to the discovery of the new "miracle drug," cyclosporin, what was previously an experimental procedure now gives hope to thousands of infirm Americans, young and old alike, whose own organs have ceased to function properly. We are, indeed, in a new era of organ transplantation.

We have also learned that because the medical advances in transplantation have occurred so rapidly and so recently, a gap now exists between the number of people awaiting transplants and the number of organs available for transplants.

Despite the heroic efforts of those involved in organ procurement, there is a substantial and continuing shortfall in the number of kidneys, livers, and hearts that are made available for transplantation. This has two woeful effects. First, it means that many needy patients do not survive their infirmities. Second, it renders a human organ a very valuable item indeed.

Given the increasing demand for transplantable organs, it was perhaps inevitable that someone would try to reap financial gain out of the tragedy of others. Indeed, one scheme for buying and selling organs has already been proposed and others are being contemplated. Actually, two have been proposed. One is being actively proposed right now.

I believe that this is a practice which we must not allow in this country. The sale of human organs runs counter to virtually every value in our system of social and medical ethics. It blurs the distinction between people and things, as human organs become simply another commodity to be bought and sold in the marketplace. It would make the poor a source of spare parts for the rich, and would auction off life to the highest bidder.

The purpose of this hearing today is to examine the proposals to buy and sell human organs and to address the issues raised by them.

First, we will address the legal issues involved with the sale of human organs. After a thorough review, the subcommittee has established that selling human organs is not presently illegal under either Federal or State law. Of course, the ranking minority member, Congressman Skeen, and I have introduced legislation that would, among other things, correct that circumstance and prohibit the sale of organs. That legislation will assuredly come up in today's discussions.

Second, because no law presently prohibits the buying and selling of human organs, we will examine how our society would view the ethics of this practice, should it not be prohibited. Often, when there is little legal guidance, the Congress and the Government and society must turn to our ethical principles for guidance, for they reflect the collective experience of us as a country and as a society.

Third, and finally, we will consider the perspective of patients who have either undergone an organ transplant or are awaiting an organ transplant. These are the people with the most at stake in this debate, and their opinions are instructive.

Before welcoming our first panel of witnesses, I would like to call on the ranking minority member of the subcommittee, Congressman Joe Skeen.

Mr. **Skeen**. Thank you very much, Mr. Chairman.

Along with the remarks that you have made this morning, I want to establish that I haven't made any secret of my opposition to any proposal that advocates the sale of human organs for transplantation.

While this is not a legislative hearing, it should be clear to many in attendance that title III of the National Organ Transplant Act, introduced by you, and of which I am an original sponsor, prohibits this practice.

I was pleased to learn that the Department of Health and Human Services is opposed to the sale of human organs. As you may know, Dr. Edward Brandt, Assistant Secretary of Health, presented the Department's position on the sale of human organs before the House Subcommittee on Health and the Environment on October 17, 1983.

In his testimony, he stated:

> Secretary Heckler and I are opposed to the sale of human organs because we believe that such activity is immoral and goes against the principles of medical ethics. We are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their actions.

In that regard, Mr. Chairman, I am looking forward to learning this morning about the health risks involved should a commercial program for the buying and selling of human organs become a reality, in addition to what I think are the obvious moral and ethical reasons for not permitting the commercial sale of such organs.

Thank you very much, Mr. Chairman.

Mr. **Gore**. Thank you. And without objection, at the appropriate point I think it would be good to put the statement of the administration in the record.

Mr. **Skeen**. I want to include that in my request, Mr. Chairman. We have that statement, and we will submit it for the record.

Mr. **Gore**. That would be fine. We had hoped that they would come and appear as witnesses, but——

Mr. **Skeen**. I think there are scheduling problems, Mr. Chairman.

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary
Washington, D.C. 20201

November 4, 1983

The Honorable Joe Skeen
Subcommittee on Investigations
and Oversight
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Skeen:

This is in response to your letter to the Secretary inviting her to testify at the Subcommittee's November 9 hearing on the sale of human organs. Because she will be on foreign travel, the Secretary has asked me to express her regrets that she will not be able to attend.

On her behalf, I would like to note that on October 17 before the House Subcommittee on Health and the Environment, Dr. Edward N. Brandt, Assistant Secretary for Health, presented her position on the sale of human organs:

> "Secretary Heckler and I are opposed to the sale of human organs because we believe that such activity is immoral and goes against the principles of medical ethics. We are particularly concerned about those persons willing to sell their organs who may not fully understand the serious consequences of their action. However, we recognize we will have to consider further whether Federal sanctions are needed or whether such activities should be dealt with at the State and local levels."

We hope this will be helpful to you as you address this important and complex health issue.

Sincerely,

Teresa Hawkes

Teresa Hawkes
Acting Assistant Secretary for
Legislation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Washington, D.C. 20201

STATEMENT FOR THE RECORD OF

CAROLYNE K. DAVIS, PH.D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

BEFORE THE

HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY

SUBCOMMITTEE ON INVESTIGATIONS

AND OVERSIGHT

NOVEMBER 7, 1983

INTRODUCTION

Mr. Chairman, I am providing this statement for the record; and, as you requested, the information is focused on the issue of allocation of human organs for transplantation, particularly as it relates to nonresident aliens. In testimony before the Subcommittee last April, I emphasized the unique role of the Medicare End-Stage Renal Disease (ESRD) program in providing protection to virtually all persons with ESRD. I wish to build upon that statement so I will not go over a description of the program or related statistics. We share a common concern and interest about this issue.

ORGAN PROCUREMENT

As you know, kidney procurement is performed by organ procurement agencies (OPAs) which are approved to participate in the Medicare ESRD program. These agencies perform or coordinate the harvesting of donated organs as well as their preservation and transportation. They also maintain a system for locating prospective recipients for harvested organs. Medicare reimbursement for procurement services provided by these entities is based on reasonable cost.

THE MEDICARE PROGRAM ASSUMES INITIAL LIABILITY FOR ALL THE COSTS OF KIDNEY ACQUISITION. WE BELIEVE THAT THIS IS THE MOST ADMINISTRATIVELY FEASIBLE APPROACH SINCE MEDICARE PAYS FOR THE VAST MAJORITY OF TRANSPLANTS. WE ARE AWARE THAT SOME KIDNEYS WILL BE TRANSPLANTED TO PERSONS NOT ELIGIBLE FOR MEDICARE BENEFITS. WHEN THIS OCCURS, WE SEEK TO RECOUP THOSE COSTS THROUGH A SYSTEM OF "OFFSETS" WHERE A HOSPITAL'S TOTAL REVENUES RECEIVED FOR KIDNEY TRANSPLANTATION TO NON-MEDICARE PATIENTS ARE OFFSET AGAINST MEDICARE COSTS. IN THIS WAY, TRANSPLANT HOSPITALS AND OPAS RECOVER THEIR COSTS AND ARE "MADE WHOLE" AT YEAR'S END AND MEDICARE HAS NOT, IN THE END, PAID THE COSTS OF NON-MEDICARE BENEFICIARY TRANSPLANT KIDNEYS.

IN THE SEPTEMBER 1, 1983 FEDERAL REGISTER, WE PUBLISHED AN INTERIM RULE ON PROSPECTIVE PAYMENT FOR MEDICARE INPATIENT HOSPITAL SERVICES. IN VIEW OF THE UNIQUE CHARACTERISTICS OF ORGAN PROCUREMENT ACTIVITIES AND THE DESIRABILITY OF MAINTAINING AN ADEQUATE SUPPLY OF KIDNEYS, WE PROPOSED THAT KIDNEY ACQUISITION COSTS BE HANDLED OUTSIDE THE PROSPECTIVE PAYMENT SYSTEM. AS A RESULT, KIDNEY ACQUISITION COSTS HAVE BEEN REMOVED FROM THE STANDARDIZED PAYMENT AMOUNTS AND FROM THE COST WEIGHT FOR DIAGNOSIS-RELATED GROUP (DRG) 302 --KIDNEY TRANSPLANT.

In recent weeks, several national publications and news programs have drawn attention to the fact that some foreign nationals receive kidney transplants in the U.S. This has caused public concern about whether the Medicare program is paying for these transplants. Anticipating this type of situation, Medicare program instructions formulated at the inception of the ESRD program in 1973 clearly require transplant hospitals to offset income received from kidneys transplanted in non-Medicare patients, including foreign nationals, against Medicare part A costs. Thus, every attempt has been made to prevent inappropriate Medicare Trust Fund expenditures.

However, as a practical matter, if a transplant bill is not paid by a non-Medicare patient, no offset of Medicare costs can be made. To minimize this problem, a number of transplant hospitals customarily require that the charge for a transplant not covered by Medicare be paid prior to the actual surgery. At Johns Hopkins University Hospital, for example, we understand a charge of $45,000 must be paid before a kidney transplant is performed on foreign nationals.

KIDNEYS FURNISHED TO FOREIGN COUNTRIES

A QUESTION OFTEN ASKED IS WHETHER AMERICAN KIDNEYS SENT FOR USE IN FOREIGN COUNTRIES COULD HAVE BEEN IMPLANTED IN AMERICAN CITIZENS. AS A GENERAL RULE, KIDNEYS ARE SHIPPED TO A FOREIGN COUNTRY ONLY IN CASES WHERE NO SUITABLE ORGAN MATCH IS FOUND IN THE UNITED STATES. THE OPAS ARE WILLING TO SHIP A KIDNEY TO A FOREIGN COUNTRY BECAUSE THEY DO NOT WISH TO WASTE THE KIDNEY. IN THESE CASES, THE TRANSPORTATION COSTS WILL USUALLY BE PAID BY THE RECIPIENT. HOWEVER, WHILE FEW COUNTRIES REIMBURSE FOR ANY OTHER COSTS ASSOCIATED WITH KIDNEY ACQUISITION, SEVERAL COUNTRIES DO PAY THE FULL ORGAN PROCUREMENT COST BILLED TO THEM.

THIS SITUATION PLACES THE MEDICARE PROGRAM AT SOME FINANCIAL RISK BECAUSE OF TWO FACTORS. FIRST, THE COST OF SERVICES PERFORMED TO DETERMINE THE SUITABILITY OF A CADAVER KIDNEY ARE NOT DIRECTLY IDENTIFIABLE TO A SPECIFIC PATIENT AS THEY ARE FOR A LIVING DONOR KIDNEY ACQUISITION. SECOND, AND OF EQUAL IMPORTANCE, MANY ACQUISITION COSTS, INCLUDING TISSUE TYPING SERVICES, ARE INCURRED BEFORE A SUITABLE RECIPIENT IS IDENTIFIED. SUCH DONOR COSTS ARE NOT BILLED DIRECTLY TO THE PROGRAM. INSTEAD, THESE COSTS FLOW INDIRECTLY TO MEDICARE THROUGH THE TRANSPLANT HOSPITAL'S KIDNEY ACQUISITION COST CENTER.

IN SHORT, BECAUSE OF THE UNIQUE NATURE OF THE ORGAN PROCUREMENT PROCESS, THE MAJORITY OF ACQUISITION COSTS ARE INCURRED BEFORE A SUITABLE DONOR IS FOUND. AS A RESULT, SOME MEDICARE PROGRAM PAYMENTS WILL BE MADE WHETHER A KIDNEY IS USED BY A MEDICARE BENEFICIARY, SENT TO A FOREIGN COUNTRY FOR TRANSPLANTATION, OR DISCARDED.

SURVEY OF NON-MEDICARE ESRD PATIENTS

THE HEALTH CARE FINANCING ADMINISTRATION (HCFA) DOES NOT REQUIRE THE COLLECTION OF DATA ON NON-MEDICARE PATIENTS RECEIVING RENAL TRANSPLANTS. AT THE REQUEST OF YOUR STAFF, MR. CHAIRMAN, HCFA HAD THE 157 CERTIFIED RENAL TRANSPLANT CENTERS IN THE UNITED STATES SURVEYED AS TO PAYMENT SOURCE AND RESIDENT STATUS FOR NON-MEDICARE PATIENTS RECEIVING RENAL TRANSPLANTS DURING CALENDAR YEARS 1981, 1982, AND THE FIRST SIX MONTHS OF 1983.*

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* THERE IS A DISTINCTION BETWEEN THE NONIMMIGRANT ALIENS WHO ARE FOREIGN NATIONALS COMING TO THIS COUNTRY ON A TEMPORARY VISA, SPECIFICALLY FOR A RENAL TRANSPLANT IN THIS CASE, AND THOSE FOREIGN NATIONALS WHO ARE FOREIGN CITIZENS RESIDING IN THE U.S. WHO MAY RECEIVE RENAL TRANSPLANTS.

I WOULD LIKE TO SUMMARIZE THE RESULTS OF THIS TWO-WEEK DATA GATHERING EFFORT, ALREADY MADE AVAILABLE TO YOUR STAFF.

OUT OF 157 RENAL TRANSPLANT CENTERS, 137 HAVE VOLUNTARILY PROVIDED DATA. SOME INFORMATION WAS REPORTED ON 407 OF THE 457 NON-MEDICARE TRANSPLANTS OCCURRING IN 1981 AND ON 326 OF THE 426 NON-MEDICARE TRANSPLANTS WHICH OCCURRED IN 1982. TEN OF THE 20 TRANSPLANT CENTERS NOT REPORTING WERE LOCATED IN THE STATE OF ILLINOIS AND IN NORTHERN CALIFORNIA. NINETY-SIX TRANSPLANT CENTERS REPORTED ALL REQUESTED INFORMATION WHILE THE REMAINING 41 CENTERS REPORTED SOME INFORMATION. OF THE 41 PARTIALLY COMPLETED REPORTS, 9 CENTERS DID NOT PROVIDE ANY RESIDENT STATUS OR PAYMENT METHOD WHILE 32 CENTERS PROVIDED INCOMPLETE INFORMATION ON RESIDENT STATUS AND/OR PAYMENT METHOD.

OF THOSE CENTERS REPORTING RESIDENT STATUS AND PAYMENT SOURCE, EFFORTS TO IDENTIFY RESIDENT STATUS WERE NOT SUCCESSFUL IN APPROXIMATELY 13 TO 21 PERCENT OF NON-MEDICARE TRANSPLANTS. EFFORTS TO IDENTIFY PAYMENT SOURCE WERE NOT SUCCESSFUL IN APPROXIMATELY 23-38 PERCENT OF NON-MEDICARE CASES, INCLUDING THE CATEGORIES OF NONIMMIGRANT ALIEN AND FOREIGN CITIZENS RESIDING IN THE UNITED STATES.

NON-MEDICARE TRANSPLANTS ACCOUNTED FOR 7 TO 10 PERCENT OF TOTAL RENAL TRANSPLANTS PERFORMED DURING THE PERIOD

SURVEYED. IN 1981, THE NON-MEDICARE GROUP OF PATIENTS ON WHOM WE RECEIVED INFORMATION INCLUDED 122 NONIMMIGRANT ALIENS, 17 FOREIGN CITIZENS RESIDING IN THE U.S., 150 U.S. CITIZENS, AND 118 WERE OF UNKNOWN RESIDENT STATUS.

IN CALENDAR YEAR 1982, THERE WERE 5,358 TOTAL RENAL TRANSPLANTS PERFORMED. THE 326 NON-MEDICARE PATIENTS ON WHOM WE RECEIVED INFORMATION INCLUDED 137 NONIMMIGRANT ALIENS, 17 FOREIGN CITIZENS RESIDING IN THE U.S., 130 U.S. CITIZENS, AND 142 WERE OF UNKNOWN RESIDENT STATUS.

FINALLY, FOR THE INFORMATION WE RECEIVED FOR THE PERIOD OF THE FIRST SIX MONTHS OF CALENDAR YEAR 1983, THERE WERE 184 NON-MEDICARE TRANSPLANTS PERFORMED OF WHICH 79 WERE NONIMMIGRANT ALIENS, 7 WERE FOREIGN CITIZENS RESIDING IN THE U.S., 74 WERE U.S. CITIZENS, AND 24 WERE OF UNKNOWN RESIDENT STATUS.

BASED ON THE DATA REPORTED, THERE SEEMS TO BE A CONSISTENCY IN THE ABSOLUTE NUMBER OF KIDNEY TRANSPLANTS RECEIVED BY FOREIGN NATIONALS FROM YEAR TO YEAR, AT APPROXIMATELY 150 PER YEAR. IN ADDITION, THE PERCENTAGE OF NON-MEDICARE RENAL TRANSPLANTS RECEIVED BY FOREIGN NATIONALS HAS ALSO BEEN RELATIVELY STABLE.

TO THE BEST OF OUR KNOWLEDGE, THERE IS NO PREFERENTIAL TREATMENT BEING ACCORDED FOREIGN NATIONALS IN THE

DISTRIBUTION AND ALLOCATION OF KIDNEYS FOR TRANSPLANT. TO BE SURE, THE DECISION OF WHICH RECIPIENT IS GIVEN WHICH KIDNEY IS A COMPLEX ONE INVOLVING MEDICAL JUDGMENT AND SEVERAL CLINICAL FACTORS. THEREFORE, IT WOULD BE DIFFICULT FOR A NONCLINICAL INDIVIDUAL TO DRAW THE DEFINITE CONCLUSION THAT A PARTICULAR PERSON WAS GIVEN PREFERENTIAL TREATMENT.

CONCLUSION

MR. CHAIRMAN, I WOULD LIKE TO CONCLUDE BY REEMPHASIZING THAT MEDICARE REIMBURSEMENT POLICIES ARE DESIGNED TO PAY ONLY FOR THOSE ESRD PATIENTS ENTITLED TO MEDICARE BENEFITS. A MEDICARE CARD IS THE PREREQUISITE DOCUMENT FOR COVERAGE. UNLESS FRAUD IS INVOLVED, THE PROGRAM DOES NOT PAY FOR CARE PROVIDED FOR NON-MEDICARE PATIENTS, INCLUDING FOREIGN NATIONALS. THE FACT THAT A PERSON IS A FOREIGN NATIONAL DOES NOT PRECLUDE HIM OR HER FROM ESTABLISHING ENTITLEMENT TO MEDICARE UNDER THE ESRD PROVISIONS IF THE INSURED STATUS REQUIREMENTS OUTLINED IN SECTION 226A OF THE SOCIAL SECURITY ACT ARE MET.

I LOOK FORWARD TO WORKING WITH YOU AND OTHERS IN THE CONGRESS AS WE LOOK CAREFULLY AT THE AREA OF ORGAN TRANSPLANTATION AND PROCUREMENT AND THE PROBLEMS WE ALL FACE IN CONTINUING TO ASSURE QUALITY CARE FOR BENEFICIARIES, WHILE RESTRAINING COST OF THE SERVICES.

Mr. GORE. I would like to call now on Congresswoman Schneider.

Mrs. SCHNEIDER. Thank you, Mr. Chairman.

I am pleased to participate today in the hearing examining the scientific, legal, and ethical problems that are associated with the procurement of organs for transplantation into the human body.

Meeting the tremendous need for organs for now—that now exist has become a public policy priority, both in my home State of Rhode Island and also nationwide. The knowledge of the various experts assembled here today will most—will be most helpful in adding to the body of opinion we have already acquired concerning the proper direction that the Federal Government should take in establishing national policy for organ procurement and for transplantation.

We have to begin today's hearing by accepting the premise that the present uncoordinated system of matching donors with needy recipients is a dismal failure. I don't think anyone in this room would dispute this conclusion.

Although estimates are imprecise, it appears that more than 70,000 Americans are currently waiting for an organ transplant. Tragically, one-half of these people will die before undergoing a transplant operation. And the shortage is not simply due to the fact that there are not enough organs available, because the Center for Disease Control in Atlanta estimates that only 20 pecent of those who die each year from traumatic accidents, tumors or strokes are properly utilized as donors.

If we continue this haphazard system, the CDC foresees a tenfold shortage in organs available for transplant over the decades ahead. The question we have to address is how best to meet the needs for the organs that are increasing daily.

Representative Gore, the distinguished chairman of the subcommittee, as he has already mentioned, has established legislation creating a centralized clearinghouse for matching donors with potential recipients. Today, however, we turn our attention to a more controversial proposal for solving the organ transplant crisis, which would allow the sale of organs by individuals for use in transplant operations.

Proponents of selling organs argue that the market incentives are the only way to meet the shortage if available organs—for available organs that presently exist. Underlying this belief is the notion that altruism and public awareness, while idealistically attractive, are simply not enough to motivate a large number of individuals to voluntarily give up their kidneys, eyes, and other valuable organs.

While I am willing to examine this suggestion with an open mind, it's my hope that the experts here today will address several serious concerns I have about allowing humans to engage in the sale of their organs.

Foremost among these concerns is the issue of informed consent. Is it possible to insure that an individual making a decision to sell his or her organ will be free from coercion by family, friends or adverse financial circumstances, and what about the needy individual who is unable to pay the price of an organ? Also, is it not true that monetary incentives would drastically decrease the limited supply of free organs available for transplant today?

These questions touch on but a few of the ethical, legal, and psychological issues which arise from the proposal to sell human organs on the commercial market. I'm pleased that this panel of experts has assembled today to address our concerns, and I look forward to any insight that they can provide on this most controversial of proposals.

Thank you, Mr. Chairman.

Mr. GORE. Thank you very much. I appreciate your statement. And without any further ado, I'd like to get into our first panel.

I would like to call to the witness table Mr. Peter Dobrovitz from Rochester, N.Y.; Mr. John Newmann, president of the National Association of Patients on Hemodialysis and Transplantations; Dr. Ira Greifer, medical director of the National Kidney Foundation in New York City; and Ms. Mary Ann Engebretsen from Miami, Fla., accompanied by her daughter, Trine, who is 2 years old.

I think Trine probably will be more comfortable back there, don't you?

Ms. ENGEBRETSEN. She is very busy with Sesame Street.

Mr. GORE. It is a pleasure to see you again. We are delighted that you are here.

Ms. ENGEBRETSEN. Thank you.

Mr. GORE. This panel represents the perspective of the patients on the proposal that forms the subject of today's discussion.

I would like to say that without objection the entire prepared statements of each one of these witnesses will be included in full in the record.

We'd like to begin with you, Mr. Dobrovitz, if you could proceed. If you care to summarize any portion of your statement, please feel free to do so. We are delighted to have you here.

STATEMENTS OF PETER DOBROVITZ, KIDNEY RECIPIENT, ROCHESTER, N.Y.; JOHN NEWMANN, PRESIDENT, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, NEW YORK, N.Y.; IRA GREIFER, M.D., MEDICAL DIRECTOR, NATIONAL KIDNEY FOUNDATION; AND MARY ANN ENGEBRETSEN, MIAMI, FLA., ACCOMPANIED BY HER DAUGHTER, TRINE

Mr. DOBROVITZ. Thank you.

Congressman Gore and members of the subcommittee, on February 24 of this year I received a phone call at 5 a.m. from the transplant coordinator at the University of Pittsburgh's Presbyterian Hospital. Within two hours I would be on a flight to Pennsylvania. Within 6 hours I would be wheeled on a stretcher into Presby's operating room complex.

Across the corridor I would see a white styrofoam case with a sticker on it that read, "Human Organ for Transplant". It was a kidney for me, a kidney that would put an end to 8 long years on dialysis.

As part of my submitted testimony I have included a transcript of a three-part account of my years on dialysis published by the Gannett News Service newspaper chain. It is not my intention to spend my time here outlining the difficulties and restrictions, both physical and psychological, that dialysis places on a patient's life. I hope that purpose can be served by my previous writings.

I will just say that the transition from a life of dependency on dialysis to a life of independence with a functioning kidney over the last 8 months has been nothing short of miraculous. My overall stamina and physical well-being have never been better. But, more importantly, I can now approach life with a much better attitude of self-confidence, self-assurance, and optimism.

On that February day in Pittsburgh, I was fortunate. Somewhere, the family of one who had just died, in that horrible moment of grief and suffering, had thought beyond their immediate concerns and gave the go-ahead for the cadaver organs to be used for transplantation.

There was no consideration of financial gain. No money changed hands. The donation—and that, I think, is the key word—would not offset funeral expenses, medical bills, or pay off some outstanding debts. I will be forever grateful for what I consider to be the ultimate act of generosity, what the Kidney Foundation calls "the gift of life."

You are here to receive testimony concerning proposals to set up and implement clearinghouses for the sale and distribution of organs. You are also here to receive testimony concerning ways to improve the current system of organ donation as it exists in America. On the first issue, I can offer this subcommittee two insights into the proposed plan, as one who has benefited from a recent kidney transplant.

Having experienced the total transformation in my life from dialysis to posttransplant, I would have explored the possibility of purchasing a kidney had the situation presented itself. But, as I have stated previously, I was fortunate.

After an evaluation in Pittsburgh in November 1982, I was placed on the waiting list for a kidney in December. My wait was short, barely 3 months, but I know that the wait for many other dialysis patients is much longer, often stretching out over several years.

The waiting period for that phone call is undoubtedly the most difficult of all. When you are on dialysis, there is a regularity, a steady routine that can make you approach treatments in much the same way you would a second job. It merely becomes a fact of life that you must deal with as best you can.

But when you commit yourself to a transplant list, you suddenly throw your whole life into limbo. That call can come at any moment. When it does come, you must literally drop everything and suspend any of your current activities—a career, a family life, anything—for at least a month or longer as you go through the transplant and subsequent recovery.

In my case, it became exceedingly difficult to focus and to concentrate on my job or my personal relationships. Everything seems so transitive. Had I been forced to wait longer, I am sure the alternative of going out and answering an ad or placing one myself would have become more and more appealing. It would have represented a chance to make a concerted effort to end the speculation.

Under the current system the recipient is at the mercy of countless unknown forces at work. You have no way of knowing if you are at the head of a long line or at the end. You don't know if the next kidney of your type has your name on it. You can only wait.

But at this point I must make it clear that this should in no way be construed as an endorsement of any organ for sale program. I merely state that if things had been different, I would have considered such a program as an option and probably would have spent the money to bring about a transplant.

I know now that I really can't put a price on what the transplant has meant to me in terms of freedom and improved outlook on life. I do know that I have paid loans for a college education, a new car and a mortgage on a home. Paying back a loan for a new kidney, viewed in this perspective, seems like a small price to pay when compared to the benefits derived from these other acquisitions. But that leads also to my second observation.

I don't think it is fair to condemn any doctor or healthy individual who is interested in beginning an organ for sale procedure. Why? I think we must first look at existing conditions in our society and the medical community.

In a recent column in *USA Today*, I referred to Dr. Barry Jacobs, one doctor who advocates organs for sale, as one who was working in "supply side nephrology". That, I think, is what the program is all about.

He has perceived, quite correctly, that there is an overwhelming need in America for donor organs and he has gone about filling that need in a most acceptable capitalistic manner. He has merely identified the market, developed the product, and set a price on the product and his distribution service.

To me, it is only in keeping with a society and economy that encourages a form of social and economic Darwinism. Government deregulation in so many areas has produced a "charge what the market will bear" mentality. Sure, there is some competitive pricing, but overall we are living in a time when those with the resources and with the moneymaking plan can usually take their chances and make whatever money they can. Dr. Jacobs is no different, and it is foolish and naive to view medicine as existing on some higher plane, outside the considerations of profit and price.

What can this committee do in bringing about legislative action? I think there are several things, including improving the current system, but much more. I would like to take just a few more minutes to outline the steps that I think must be taken.

First, before you move to ban Dr. Jacobs or those who would like to market their organs, I would suggest you first make an overall examination of the delivery of critical health care services in this Nation. Specifically, I think the Congress needs to address the current role of hospitals and insurance carriers in the field of so-called experimental surgery.

While we are concerned with the matter at hand, hospitals across the Nation are forcing critically ill and, in many cases, terminal patients to produce large sums of money up front in order to receive medical care that will keep them alive.

While in Pittsburgh I saw the story of a young woman who had to rely on the fundraising efforts of her community to get the cash for a bone marrow transplant in Seattle. Without the operation, she would die. There was the case of the heart patient in the Midwest who received a $100,000 check from TV producer Aaron Spelling in order to pay for a risky heart operation. Without it, he also would die.

Again and again this scenario is played out across the Nation. So, for those who view Dr. Jacobs and those like him as crass mercenaries, barbarically twisting the Hippocratic oath around their checkbooks, are the actions of these hospitals any less mercenary?

What of the liver transplant candidates who just can't come up with the $20,000 required in advance for a transplant? The Federal Government recognizes chronic renal failure as a disease worthy of Federal funding. Between the Government and Blue Cross, my transplant cost little more than my air fare to Pittsburgh. That's because a cyclosporin-aided transplant is no longer viewed as experimental.

But what of the others? Must patients in America die because they can't afford the treatment? With the billions of dollars that we spend on MX missiles and other Pentagon projects designed to up the kill while preserving our freedom, is there no money available to up the count of the living?

There is no doubt about this. There will be Americans who will die this year because they cannot afford the admission price to the operating room, because they just can't hold enough bake sales or raffles to get donations, and because there are only so many Aaron Spellings to go around.

Are we so heartless to do nothing while the critically ill must not only suffer, but beg for the generosity of others? This is a human tragedy in a Nation of such great wealth and resources.

The second point is, while we examine the questions surrounding a program like the one proposed by Dr. Jacobs and the ramifications of health care for the rich only, again, we must first look at existing practices going on right now in American hospitals.

Why is it that Canadians with money can come across the border to receive cornea transplants in America for a price because such services are hard to come by in their homeland? Why is it that Arabs from the oil rich Middle East can come to American hospitals and pay $50,000 or $60,000 cash, up front, and are greeted with open arms by hospitals ready to accommodate their desire for kidney transplants? Why is it that these people can arrive with no donor organ on the way and after waiting a week or two, somehow a kidney suddenly materializes? Are these people with big money being pushed to the head of the line? Are they buying up a kidney that just as easily could have been earmarked for a waiting American with the same tissue type?

In a sense, what Dr. Jacobs and others propose is nothing new. It goes on already in hospitals across the USA. High paying patients are buying their good health with the good graces of hospitals who must enjoy the prospect of instant payment with no drawn out paperwork from the Government or insurance carriers.

I am not suggesting that we close our borders to those who seek medical treatment in America, but I do feel steps must be taken to insure that Americans in desperate need of available organs for transplantation not be pushed aside merely for the financial considerations of a hospital's accounting department, because it is easier, or the board of directors, because it is profitable.

The solution, I would submit, is that, those who come to this country and are willing to pay, must also be willing to wait. Perhaps they can be houseguests of volunteers in American cities, willing to put the patients up while they wait. Or perhaps they can use their vast resources to obtain temporary housing of their own. But once here they should go on the list the same way everyone else does. There should be no priority preference given to those who come bearing cash. They must wait as everyone else must, for 3 days, 3 months, or 3 years, if need be.

Finally, I submit to you the most important recommendation I can make. If this committee is determined to ban the sale of donor organs, there is an easy way to do it. You must merely eliminate the demand by dramatically increasing the supply.

People like Dr. Jacobs are merely umbrella salesmen in a rainstorm. They are attempting to make the best of a bad situation. But the situation does not have to be so bad. Everyone agrees that the current system of organ donation on a voluntary basis is inadequate. Studies show that people do not consent to organ donation for a variety of reasons. Even if someone expresses the desire to become an organ donor upon brain death, that wish must still be fulfilled by remaining family members, often overcome with grief.

Doctors on the scene, often the best possible spokespersons for organ donation, often fall down on the job. Some feel that their work ends on the operating table and preserving another life by encouraging organ donation is just not their job.

Each year some 20,000 Americans are declared brain dead. That is a potential for 20,000 liver transplants; 40,000 kidneys and corneas. Yet, we know that statistics show barely one-tenth of those organs are harvested.

With 10,000 dialysis patients currently awaiting a kidney, if we could even get the harvesting rate from 10 percent to 50 percent, the battle would be won, and Dr. Jacobs would have to find other ways to fund his retirement. But today, organs are being packed away in expensive caskets to rot in the corners of cemeteries, instead of enriching the lives of others.

If this committee is truly sincere in its effort to upgrade the lives of those awaiting transplantation, if it is determined to put an end to checkbook transplantation, there are but two clear courses of action, one long range and one short immediate.

In the long run, the Federal Government must commit large sums of research money to the pursuit and development of monoclonal antibodies. Currently used in very limited cases, the potential of these as a permanent cure to the transplantation backlog is mind-boggling.

I am no surgeon or research biologist, but as it is explained to me, we could reach a point when these antibodies would be introduced into the system of a recipient. They would program the recipient's body chemistry to accept any organ available for transplantation.

There would be no more waiting. The next available kidney would have your name on it. No endless matching. No concern about rejection. Those whose kidneys fail would no longer even need dialysis. The placement of a new kidney into the body would become automatic.

When you consider the billions the Government has spent over the years to maintain care for dialysis patients, the prospect of this research providing the ultimate solution is truly exciting. It seems imperative that the Government do all it can, and then some, to help the doctors engaged in this work reach a solution as quickly as possible.

As an immediate step, I suggest that the United States adopt a standard organ donation procedure similar to those currently in effect in some European nations. It is the direct inverse of the way we currently harvest organs in America.

Currently in America the assumption is made that you are not a donor unless you specify that you wish to be one. In the proposed system, the assumption is made that everyone is a donor unless specified that you do not wish to be one.

Upon brain death, appropriate organs are removed as standard procedure in the same way that an autopsy is performed as standard procedure when certain criteria are met. There is no questioning of bereaving family members in the moments after death. The organs are removed and the body is then ready for the work of the funeral director.

Those attending funeral services would have no way of visibly knowing the harvesting of organs had ever been done. Those who would reject organ donation out of fear for the disfigurement of the loved one would have their fears relieved. Every possible available organ would be harvested, triggering a dramatic increase in the national supply.

The option would still be left open for those who, for whatever reason, refuse. Surviving family members would merely have to state their opposition, for whatever reason they choose, and the procedure would not be performed. This would insure the preservation of personal rights on religious, ethical, and even unstated grounds. It would work to the satisfaction of all concerned.

Every year thousands of organs are never located because someone forgot to ask, because in that moment of grief someone forgot to offer. It need not be that way. Our legislative bodies have the power to change it. You lower the speed limit and raise the drinking age to prevent death on the highway. Passage of a uniform organ donor procedure would revolutionize the delivery of transplant service in this Nation.

And from a purely financial perspective, the cost of a single transplant and maintenance medication is just a fraction of the funds that must be spent each year on each dialysis patient in America.

As early diagnostic techniques continue to improve, we will be faced with even more people placed on dialysis before succumbing to kidney failure. This option, the national harvesting system, seems like the only realistic way to meet the demand while also easing the ever-growing budgetary strain of ongoing renal treatment in the Federal Government.

In closing, I wish to extend my thanks to Congressman Gore and to this subcommittee for giving me the opportunity to voice my opinions and offer my experiences as insight. I wish to commend all of you for taking the time to look at a question that deserves the attention of all our legislators. We are talking about life and death.

There are those who say organs for sale will only threaten the existing voluntary system, and I concur. Perhaps I can pass along just one letter I received while in Pittsburgh from a Rochester mother whose daughter had been declared brain dead.

The mother, in that most difficult time, gave the go-ahead for organ harvesting. The young girl's corneas restored the sight to two others. Her kidneys took two others off dialysis. Her liver was used to make someone else whole, and even her pancreas was used for research. At least five lives were directly affected and enriched by the unselfish act of a grieving mother.

But she said in the aftermath of the tragedy, in that letter, that it was the only thing that made sense. Not dollars and cents, but commonsense, peace of mind, and you can't put a price on that, either.

For those who might wish to consider going to work for Dr. Jacobs or someone else as an organ donor for hire, I cannot condemn your actions. It is your body. But realize before you begin that there will be few there to pat you on the back, either.

As I said at the beginning of this statement, I was lucky. My donor's family in those difficult moments passed on the gift of life with no strings attached. If I bought a kidney, my debt would end as I tore the last coupon out of the loan payment book.

I could understand the motives of the seller and the doctor, but I doubt if I could respect them. The debt I owe that unknown donor of my kidney goes on forever. I will be forever grateful, and I can only hope that work like this, speaking on behalf of the kidney patients who still wait, can somehow begin to repay the generosity of that singular act.

Thank you.

Mr. GORE. Thank you very much. We will hold up on questions until others have made their statements.

Let me invite those who are standing, we have some seats. If you want to come and join us, please feel free.

I would like to call next Mrs. Mary Ann Engebretsen, from Miami, Fla. Again, let me welcome you to the subcommittee. It's a pleasure to see you again, and please feel free to proceed with your statement.

Ms. ENGEBRETSEN. Thank you, Mr. Chairman.

I would just like to say before I get started that what you are hearing today is a revised edition of my original statement. Please understand my position. It would be quite foolish of me to antagonize those persons presently working with the present procurement system as those persons are the very same that I am depending upon to save my daughter's life.

I am here today to speak on behalf of my daughter, Trine Linn Engebretsen, who is 2½ years old and in need of a liver transplant. As I am sure you are aware, on any given day there are at least 50 other children in similar circumstances also in need of liver transplants to save their lives. My comments today reflect my personal opinions, although I am sure there are many parents of children awaiting transplants who share my concerns.

Becoming a candidate for a liver transplant can in itself be a difficult task. In my daughter's case, incorrect lab results delayed discovery of the cause of her illness for an entire year. Another year passed, and then only at my request was the option of a liver transplant discussed.

Having the knowledge that my daughter is dying of an incurable liver disease, the 3-month wait for a transplant evaluation seemed interminable. Little did I know that that waiting time was to be the easy part.

I shall be honest enough to admit at this point I did not fully realize that becoming an acceptable candidate for transplantation did not guarantee the opportunity for this life-saving procedure. I did, however, understand the risks involved: The ever-present worry of infection or rejection of the newly transplated organ. It was the scarcity of donor livers available for transplantation in pediatric patients that was at that time both shocking and frightening to me.

The waiting list is long, and my daughter's months left to live are numbered, and each week that goes by I see her chances for this surgery slipping further away. As a parent of a child in need, I have made every effort to increase awareness of the great need for organ donations. I have opened my home to the press and in every case I have asked that the local procurement personnel be allowed to speak concerning the medical issues of organ donation. I have traveled to several other States for the same purpose. It has been an educational experience for me, and the more I learn, the more questions I have.

In Congressman Gore's words, "The present system is a fragmented patchwork of 110 separate procurement networks." Many of these procurement organizations feel that the job is being done adequately at present, and there is no need for another national network to be set up. This bothers me for several reasons.

First, at present each individual procurement organization can make the decision either to keep a donated organ for use locally or contact one of the national 24-hour hotlines to locate a potential recipient. Dependent on how conscientious that particular procurement person is, that donated organ may or may not be matched up with the patient in the greatest need at that time. For this reason, many potential kidney recipients place themselves on as many waiting lists as possible. Certainly better coordination and communication between existing procurement centers would be beneficial to all concerned.

Second, if the present system is totally adequate, why are so many persons forced to use the media to attract attention to their particular need? Media attention is focused not only on the inability to obtain necessary organs as well as financial requirements for a life-saving surgery which is well beyond the limitations of average citizens.

Finally, why has so much attention been paid to those persons who wish to sell their kidneys and corneas? This is a proposal which I find totally morally and ethically wrong, yet it is an idea entertained by others in desperate need. The potential exists to meet the demand by using donated organs through the implementation of a national awareness program. This program would educate both persons in the medical profession as well as the general public.

In conclusion, clearly a national strategy for dealing with the complex issues involved in organ transplantation is necessary. With the advances in transplant surgery, the need for donated organs shall be an ever-increasing one. Education of the general public concerning organ donation procedures is essential for the success of transplant programs. Without question, a national awareness program should be developed and implemented without delay.

Thank you very much.

Mr. GORE. Thank you very much. We will come back with questions after the full panel has completed their statements.

I would like to call now on Dr. John Newmann, president of the National Association of Patients on Hemodialysis and Transplantation from New York.

Dr. Newmann, we are delighted to have you here. Please proceed.

Dr. NEWMANN. Thank you. Mr. Chairman, members of the committee, I thank you for inviting me to appear here today to share the concerns of the National Association of Patients on Hemodialysis and Transplantation——

Mr. GORE. Excuse me. You might swing that microphone around. There you go.

Dr. NEWMANN [continuing]. More commonly known as NAPHT. I serve as president of the association and have been a home hemodialysis consumer for the past 12 years. I am an economist by training, having worked 12 years at the Ford Foundation. I have received a masters of public health degree from Harvard University and currently work as a health management consultant.

NAPHT is an association of kidney patients with over 11,000 members from every State and from the U.S. territories. We currently have 34 chapters in 19 States. Our members include patients who are treated with every available modality, including kidney transplantation, both from living-related donors and cadaveric donors. The topic being addressed here today is of rather obvious concern to our membership.

It is the position of our organization, as adopted by unanimous vote of our board of directors at our recent national convention, that the commercial sale of organs for transplantation should not be permitted. There are several reasons why we have taken this position, and I will address each one in turn.

ETHICAL PROBLEMS WITH SELLING ORGANS

While representatives of the medical profession can more directly address the issue of medical ethics, we have noted that the primary kidney transplantation groups, including the American Society of Nephrology, the American Society of Transplant Surgeons, the International Society of Transplant Surgeons, and the National Kidney Foundation have all denounced the sale of organs.

Medical ethicists have frequently focused on the issue of informed consent and concluded that whenever there is even implied coercion, such as the use of prisoners for experimenting with new medications, that informed consent is difficult, if not impossible, to obtain.

Would not the same thing be true with the introduction of a monetary reward for the donation of a kidney? Would a person be able to weigh the personal risk objectively with a monetary inducement being offered?

Kidney failure strikes persons in all walks of life, although its occurrence is more frequent per capita among blacks than among whites, primarily due to the higher incidence of high blood pressure among blacks. If purchasing an organ ever became a primary means of obtaining a transplant, those of greater wealth would obviously be at a substantial advantage.

We have lived through the days of selection for treatment prior to the enactment of H.R. 1 in 1972 and find any return to that type of selection process, which invariably favors whites over blacks and the wealthy over the poor, to be repugnant and morally reprehensible.

In addition to the question of the fairness of the sale of organs, we cannot help but fear that allowing such sale would actually decrease the number and quality of organs available for transplantation.

In the first place, allowing a monetary reward for the donation of a kidney would create a powerful incentive to provide an inaccurate medical history. Although medical testing of the donor would reveal such things as diabetes, it would not reveal every possible contraindication to donation, such as a history of kidney stones. The experience with paid blood rather than voluntarily donated blood with its eight times greater risk of post-transfusion hepatitis should be noted.

Second, the commercial sale of organs may actually reduce the voluntary donation of organs for transplantation. By appearing to provide a solution to the need for donors, less organ retrieval activities might be carried out, not more.

Asking the family of a dying or deceased person to allow for organ donation is a difficult task at best. If the public believed that the need was being met through the purchase of organs, asking for voluntary donation could only become that much more difficult a task. If the public believed that there was no need for organs, would the number of individuals who sign organ donor cards decrease?

Finally, a reduction in the use of cadaveric donors would be harmful to individuals who suffer other conditions, such as liver failure. We have a great deal of sympathy for those with that condition since we do realize that they have no alternative therapy, as we do, and that the matching requirements are more stringent.

A basic premise of those advocating the sale of organs is that there is a large unmet need for organs which can be taken from live donors; that is, kidneys. The press has quoted figures of 100,000 people on dialysis, implying that all need or want a kidney. This is simply untrue. There are approximately 70,000 persons in the United States on dialysis, 10,000 of which are on transplant lists. The other 60,000 are aware of transplantation but have not signed up.

While all of us on dialysis look to transplantation to offer the best solution to our problem in the future, not all of us want a transplant now. The immunological problems have not yet been adequately resolved, and there are alternative therapies.

I am personally among those not yet willing to risk a transplant, since I do quite well on dialysis, although I am waiting for one in the hope that the immunological problems will be solved.

Cyclosporin is being discussed by the press as the ultimate "wonder drug" for transplantation, and we welcome its availability. Given the possibility of its unwelcome side effects, however, a certain amount of caution is warranted at this time. As an aside, the question of payment for this very expensive medication—approximately $5,000 or $6,000 per year—has not been resolved.

I would not want to give the impression from what I have just said, however, that there is no need for increased organs because there is. There are people who do not do well on dialysis or who feel that the risk of a transplant is well worth the improved quality of life available to them if the transplant is a success, and these individuals are most anxious to receive a transplant. Organs should be available for them.

The problem of sufficient organs is really an educational and administrative one. As Dr. Jeffrey M. Prottas noted in his testimony before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce on July 29 of this year, and I quote, "Conservative estimates put the number of suitable donors of cadaveric organs at 20,000 a year." That would mean 40,000 kidneys could be available for transplantation each year, more than enough to meet the entire need. Commercial sale of organs with all of the resulting problems is simply unnecessary.

We welcome the interest shown by this committee in resolving the administrative and educational problems of organ procurement and support the establishment of a U.S. transplantation network as a possible means to better share available organs. A national effort to further educate the public and the medical profession is drastically needed.

Having expressed our objection to the sale of organs, I would like to turn to another issue of concern. Living donors, whether related or not, sacrifice a great deal when donating a kidney to a loved one, including loss of wages and substantial out-of-pocket expenses for nonmedical items, such as travel to the city where the transplant will occur.

We do not believe that should some choose to reimburse those donors for those expenses, that person should be in violation of the law. Yet the wording of H.R. 4080, title III, would appear to declare that a person—that person a criminal and subject to a $50,000 fine and a 5-year prison term.

It is NAPHT's position that there should be no legal obstacle to the reimbursement of actual out-of-pocket expenses, including lost wages, for a living donor and we urge this committee to modify the language of this legislation to achieve that result.

Finally, I want to thank the subcommittee for its great concern about the problems surrounding the transplantation of human organs and, more specifically, the sale of organs. NAPHT stands ready to offer its assistance in finding ways of improving the organ procurement and transplantation systems of this country as we all seek to meet this very important human need.

Thank you.

Mr. **Gore**. Thank you very much. Let me just interject a statement. We have already clarified the bill with the language making it clear that certainly it was not our intent, and is not our intent, to interfere with the payment of out-of-pocket expenses due to live donors that lose wages, et cetera. This is something that was made—that we were made aware of about a month ago in drafting the bill, and we agree with you and we are going to take care of that problem.

Dr. **Newmann**. Thank you very much.

Mr. **Gore**. The final witness on this panel is Dr. Ira Greifer, medical director of the National Kidney Foundation. We are pleased to have a chance to talk with you again, Dr. Greifer. We appreciate your presence here today. Please proceed.

Dr. **Greifer**. Mr. Chairman, committee members, my name is Dr. Ira Greifer. I'm medical director of the National Kidney Foundation, professor of pediatrics and director of the Children's Kidney Center of the Albert Einstein College for Medicine, and chairman of the Kidney Institute of the State of New York.

I have worked actively in the clinical, investigative aspects of kidney transplantation for over 22 years and have been involved in public policy, ethics, and procurement programs for 20 years.

Mr. **Gore**. Could you move that microphone just a little bit closer? There you go. Thank you.

Dr. **Greifer** [continuing]. And have been involved in public policy, ethical aspects and programs for procurement for almost 20 years, and would like to speak from this perspective for the many thousands of members of the National Kidney Foundation, which includes physicians, both transplant surgeons, nephrologists, social workers, lay members, and patients.

The National Kidney Foundation has for many years encouraged and worked for a national health policy to assure equal access to the highest quality of kidney disease care for all Americans.

Our "Gift of Life" program developed in 1965, which has included the distribution of over 30 million donor cards, has encouraged with considerable success the gift of cadaver organs on a voluntary basis. These organs have been transplanted based on medical need, criteria without discrimination based on race, sex, social, or economic status.

In the 1960's we had the great success between 1967 and 1969, the shortest period in American history that the Uniform Organ Donor Act was passed by 50 States. At that point in time, most of the States, including my own State, New York, included within the legislation that no organ can change hands for cash disbursement or gift in kind.

Therefore, the intent of the original organ donor program was that no money should change hands at any given time, at any time at all, for the benefit of the individual who is giving. This intent was thought of 15 years ago, sir, and, therefore, thought out very well from 1960 through 1968 and had 15 years more to be considered.

The National Kidney Foundation is firmly opposed to the sale of donor organs for both medical and ethical reasons, many of which have been stated up to now, and I will just try to highlight some.

The ethical aspects of the medical profession which we represent states that a doctor should do no harm to a patient knowingly or unknowingly and, therefore, our group has been opposed to that. This will probably be more discussed by Dr. Oscar Salvatierra.

What about the moral aspects? Experience with living unrelated donors reveals no improvement in graft or patient survival compared to the cadaver donor transplant, therefore misleading an individual to conceive that a live donor transplant unrelated may be better for them than a cadaver donor. The recipient's interest and right to the best organ available might be compromised by the donor's interest in a cash reward for the donation.

It has been well known in the blood bank industry that the individuals donating for cash are the same ones over and over again and, therefore, cash has never solved the financial problems of the individual donor. It is an immoral, irresponsible approach by the patients—the persons donating on the basis their problems will be finalized by a cash gift.

What is to happen thereafter? Do they give their right thumb for more money in 1985, their right eye in 1986, and possibly their toes in 1988. The question that comes up is, are we interested in dismembering individuals for the rest of their lives?

It is also immoral, unethical to place a living person at substantial risk of surgical complications when their medical histories are really not completely known and a small risk of death for a cash payment. The long-term risk, if any—and it will be discussed by Dr. Barry Brenner later today—of life with a single kidney remains to be determined by scientists.

The temptation of a cash reward for donation would violate the basic concept and sanctity of informed patient consent to invasion of his or her body. We perhaps recogize more than most that the need for donor organs is presently incompletely met. We fear, however, that placing a price on a donor organ will undermine the current system of a voluntary gift of life and will actually decrease the number of organs now available for transplantation.

The concept of the program that was presented in the *Washington Post* that this was supply-side economy, I call it supply-side cannibalism. Should the American people endorse a system in which the rich and well-to-do cannibalize the poor, the infirmed, the children, the weak, or the retarded for the sale of their organs? We object to that again on ethical and moral and practical grounds.

The other aspect that was brought, to make my testimony short, sir, is the transplantation of foreign nationals. Although this topic is not part of the discussion today, it certainly relates to the concept of this bill and I would like to address it briefly.

It has been stated that if, in fact, we are against cash payment for kidneys or any organ, how is it that in the United States individuals from foreign nationals can get transplantation on the basis of cash payment?

The National Kidney Foundation believes that kidneys and other organs donated by deceased American citizens or their next of kin are inherently intended by the donor to benefit a fellow American citizen. If a suitable recipient cannot be identified by the matching program or regional transplant programs that are involved with that program, then the patient who is a foreigner in humanitarian reasons can receive a kidney, but not before Americans, who have given to this program and given to the public trust involved.

We realize that the present program is not meeting its need. We realize that there is need of a national center for organ transplantation, a U.S. transplantation network and organ transplantation organization.

The National Kidney Foundation strongly endorses the concept of a national center for organ transplantation at the level of the Assistant Secretary of Health and concurs in its listed functions of public education, technical assistance to organ procurement organizations and annual evaluation and reporting of the efficiency and effectiveness of organ procurement and distribution.

We also support the proposed broadly based composition of its advisory councils and its defined areas of concern, including equitable patient access to organ transplantation and organ allocation and payment for nonrenal organ donation.

We also feel, however, that any organ transplant advisory council should be charged with addressing a number of other issues of immediate, even of pressing pertinence to organ donation and transplantation, including the following.

One of the things that has come to our attention is that 95 percent of the individuals who required organ donation prior to that are not organ donors. We should try to make every American an organ donor.

We feel that the Congress of the United States should participate in undertaking an investigation into the possibility that every American may be an organ donor until proven otherwise. We believe the professional and paraprofessional education programs concerning organ donation, including organ-specific potential and suitable donor critera, be met.

This again can be done with very little cost to the Federal Government by requiring every medicare provider hospital to have an organ donor procurement protocol within their hospital. That costs very little.

Early identification of donors through this concept by the emergency medical technician, the emergency room personnel, the critical care personnel can lead to far more organ donations throughout the United States. If, in fact, the hospital which may be 150 beds or more does not have an organ identification protocol, they can be disenfranchised by the medicare system, enhancing interprofessional cooperation in organ donor identification and procurement, minimizing or eliminating professional liability at all stages of potential donor identification and organ donation, perhaps including a Good Samaritan clause and appropriate legislation for enactment of a uniform brain death law by each State and other appropriate measures.

The precedent for that, Mr. Chairman, is a uniform organ donor program that has been taken up by 50 States. We suggest a uniform brain death law throughout this country.

We feel at this time that the program in fact has been very successful, but obviously, as everybody says, is the cup half empty or half full. We feel it is half full and moving closely to being fulfilled. We think that Dr. Jacobs has challenged the American people in stating, do they wish a system based on the 1960's, that is who shall live and who shall die based on their ability to pay.

We propose that the American system—is that the system should give equal access to the organs available to every American on a first-come-first-served basis and that every American should have the right to a full and good quality of life.

Thank you, sir.

Mr. GORE. Thank you very much. I appreciate your statement. And I, too, view Dr. Jacobs' proposal—and he will be testifying in the next panel—I view it as a challenge to make the current system work the way it should.

I agree with you that the cup is half full and not half empty. As others have said, the 5,000 transplants now taking place each year didn't happen by accident. It's a result of a lot of hard work, but we all know we can do better. Dr. Jacobs' proposals should serve as a warning that unless we do better we will sink into a different kind of ethical framework that might be inevitable unless we can make the current system work better.

A number of you have raised issues that are quite broad and sweeping. I want to try to focus the hearing today on the issue of buying and selling human organs.

We had a hearing on Monday that was directed at the issues surrounding transplantation of nonimmigrant aliens, or foreigners, and the record of that hearing I hope will be quite useful in discussing that issue. A couple of witnesses have discussed it here today. What I am saying is that I would like to try to keep the focus on the issue that we have called this hearing around.

Mrs. Engebretsen, before asking you specifically on this issue, let me just ask you briefly about your daughter. Your daughter needs a transplant, correct?

Ms. ENGEBRETSEN. Yes, that is correct.

Mr. GORE. And unless she gets a liver transplant she will die? Is that what the doctors have told you?

Ms. ENGEBRETSEN. Yes, that is correct.

Mr. GORE. And you need to locate a suitable donor within a matter of months. That is the impression that the doctors have given you, is that correct?

Ms. ENGEBRETSEN. That is correct.

Mr. GORE. Well, I can only stand in awe of your courage in addressing these issues and helping the country to come to a better understanding of what needs to be done in a time of such hardship for you. Please rest assured that our goal and our whole objective is to try to increase the chances that children like Trine and other Americans will be able to get the transplants they need to save their lives.

Now, let me ask you specifically on the question that we are discussing here today, why are you—first of all, you are strongly opposed to the buying and selling of human organs? Is that correct?

Ms. ENGEBRETSEN. That is correct.

Mr. GORE. Tell me—tell me why you are so strongly opposed to it.

Ms. ENGEBRETSEN. I just feel it is morally and ethically wrong to sell human body parts. I just feel that this offends my sense of right and wrong.

Mr. GORE. Can you tell me why?

Ms. ENGEBRETSEN. As you have said before, this is nonrenewable. I think the persons who are willing to sell their organs are making a foolish decision, that they are putting themselves at risk. As far as my own personal feelings about selling it, I just think that God has given you only one body and you should not sell those parts simply because it is yours. It is not replaceable.

Excuse me. I can't concentrate with this little lady here. Maybe I can work a little better if I put Trine over here to play.

I just feel it is wrong. I am sorry, I can't express it any better than that. I just feel that this is not right to me. I would not sell my body parts. I don't feel it is fair to ask someone else to do that, either. I would not want to purchase one from someone. I wouldn't want to put them at that risk.

Mr. GORE. Well, I appreciate that. In discussing this issue I have occasionally been reduced to saying I just think it is wrong. It is complicated, and I think it is wrong for a number of reasons, but I am interested in your views and I appreciate them.

Mr. Dobrovitz, you are not so sure, are you?

Mr. DOBROVITZ. I guess I am not. My objections aren't as deep seated because I guess being in that position of being a possible customer, I can see it as an option that, as I said before, I would consider. But my objection is I just think that there is a better way to do things and that we don't need this.

So, I guess I am coming at it from a different angle, but the end result is still the same, that I am not so intent on the wrongness of it because I guess maybe I see that there are a few other things, as I mentioned in my testimony, in the current medical system that I think aren't exactly quite right, either, and they all kind of fall into that same pool.

As long as we are in that situation in America today, my focus is, well, let's do something better so that we don't have to deal with this question at all.

Mr. GORE. So, your objection is principally that you see it as impractical, in that there is a better alternative that we ought to focus on instead?

Mr. DOBROVITZ. Yes, yes, very much so.

Mr. GORE. Now, if someone told you that in their view the buying and selling of human organs would make it more difficult to get to this better alternative, that would strengthen your objections to buying and selling, would it not?

Mr. DOBROVITZ. Very much so.

Mr. GORE. Dr. Greifer, do you believe that a marketplace in human organs might make it more difficult to improve the current voluntary system?

Dr. GREIFER. I think it absolutely would for a number of reasons. One is that if one looked at a cross section of the socioeconomic aspects of the individuals who need to receive organs, they are in no position to buy. Most do not have the kind of equity that they could put up or even pay over a long period of time.

Let's face it, in this country trying to even get—for the average American we are talking about a $5,000 loan, it is almost impossible and, therefore, what the system is based on is on the American trust.

Let's face the facts. If an individual wants to sell a kidney, he goes and says, "I want to sell it." He names a price. He goes to a hospital that is a provider that is supported by the American Government. He goes into a system that is supported by the American Government. The broker is free and clear on his money, the individual is free and he is clear on his money, and the American public basically is supporting two systems, a voluntary system and a public pay system. So, they are really subsidizing the rich and again—and actually hurting the poor because basically the poor won't be able to buy that kidney that the Government is subsidizing.

I think that becomes a kind of Catch 22 system which will kill the voluntary system. I think that what has to be done in the wisdom of this Congress is to again sit down, like we did in the sixties, and figure out a system. It was proposed at that time that the possibility—that the possibility of suggesting to the Congress of the United States that, like some countries in Europe, that a system is that if an individual joins a social security system, that they have an obligation of a kind of self-payment; in other words, it is almost a system whereby there is a deductible, deductible being that if in fact within your own beliefs—that is, not against it—you are signed up and that as you sign into the social security system, if you are against it, you absolutely then say I do not want my body parts used at the time of death.

Therefore, then we would truly have a national system which would be very inexpensive from the point of view that everybody now is on—has a social security number, that it is all located in one big computer and, therefore, if somebody does come in and could be donated could be recognized immediately.

Mr. GORE. You are talking about a contracting-out system?

Dr. GREIFER. No; I am saying right now that if, in fact, the U.S. Congress specifically concerned itself with the possibility that—like now many States have on their driver's license whether they are givers or not—that under the social security system it is expected that since people want the benefit of that system, which is partly organ donation, that they should participate in that system and only upon them denying that, meaning they would say I don't want to participate, which will protect their constitutional rights, then we would have a system in place which already has a computer, identification system and everything else.

Mr. GORE. Yeah. That has been referred to under the label of contracting out. Maybe it has a more recognizable name.

Rightly or wrongly, we've chosen not to recommend that approach in the legislation. My sense is that people are not ready for that yet. There may come a time when that is possible, and my judgment of its possibility right now may be wrong. I don't know. But I would like to discuss that further.

We have a vote on the floor.

Congresswoman Schneider.

Mrs. SCHNEIDER. I just was interested—if you would yield on that point—I am curious to know—in Mr. Dobrovitz' testimony he indicated that there are some European countries that do follow that policy. What are those countries?

Mr. DOBROVITZ. If I could maybe yield to——

Dr. NEWMANN. France I know definitely has it.

Dr. GREIFER. France, Denmark. Obviously the Eastern bloc countries do, but the knowledge of how that works is incomplete.

Mr. GORE. There are about 15 countries that have such a system. I guess it is more commonly known by the label "presumed consent".

Let's go over and vote and come back, OK? If you all will be patient, it will take us about 6 or 7 minutes to go over and vote and come back, so we will recess briefly.

[Recess.]

Mr. GORE. The subcommittee will come back to order, if we could get started again.

I was about to turn it over to Congresswoman Schneider, but pending her return let me ask a few more questions.

Dr. Newmann, you are also strongly opposed to establishing a marketplace in human organs. Is that correct?

Dr. NEWMANN. That is correct.

Mr. GORE. Now, tell me why.

Dr. NEWMANN. As has been pointed out before, it would—if it was a free—in a commercial market it would discriminate against the poor and they simply would not have the opportunities that the wealthy have to obtain kidneys.

The insight and beauty of the original legislation providing medicare funding for renal transplantation and dialysis simply does not do that. Everyone is entitled to that, and there is no reason why that shouldn't be true with transplantation.

I might mention that up until now there has not been any consideration of whether the Government would decide to provide a fee for an organ. I am well aware that Health and Human Services is against that. There are those that argue that if that were the case, that the Government provided a fee for organs so that it was not a free market situation, just as it provides a fee for dialysis, that that might be worth looking into. Our organization has not approved of that or taken a position on that, but it is another alternative.

Mr. GORE. Now, you have referred, Dr. Greifer, to this proposal as supply-side cannibalism. You believe that—you have also testified that when the Uniform Anatomical Gift Act was written—how many years ago?

Dr. GREIFER. Nineteen—it was established in 1967 or 1968 and I think finally passed all 50 States, including the District of Columbia, by 1970.

Mr. GORE. Well, when the first proposed uniform law was written back in 1967, the question of buying and selling human organs was extensively researched and considered at that time, and your testimony is that even that long ago doctors, ethicists and others came to the conclusion that this would be a bad idea. Is that right?

Dr. **Greifer**. Yes, sir. It was fully discussed over a number of years in the development of the Uniform Organ Donor Act. As I stated before, I have not looked at the act in every State, but I just reviewed it in New York, and even its intent states that organs cannot be bought and sold, nor gift in kind, exchange between donors and recipients.

Mr. **Gore**. The Uniform Act is—the Uniform Act is silent on this question, isn't it?

Dr. **Greifer**. I don't know. As I stated, it is different in many different States. I have not looked at all 50 States.

Mr. **Gore**. Yeah, OK. Well, I think the one that served as a model for States to pass their own State laws, I think is silent on this question. Perhaps because back in 1967, even though this was widely reviewed and researched, there was not—there were not any eminent proposals to set up purchases of human organs. So perhaps it was felt to be unnecessary at that time.

Let me call now on my colleague, Congresswoman Schneider.

Mrs. **Schneider**. Thank you.

Mr. Dobrovitz, could you please tell me—I am sure the thought must have entered your mind—how much would you be willing to pay for an organ? Had you ever put a price tag on——

Mr. **Dobrovitz**. I guess it really didn't enter my mind. I never considered a price. I think if the situation presented itself and then the price presented itself, I would have to obviously look at my financial situation and what exactly I could afford and what exactly a bank would be willing to give to me in terms of a loan to make that kind of a payment.

Mrs. **Schneider**. I guess I am having a difficult time because from the testimony that I have heard, I can certainly understand, and I can identify with the various points of view, but I think your perspective is particularly interesting as one who was in need of an organ. And, of course, you always wonder, if I were in that situation, to what length would I go, how much would I be willing to pay?

And then you are also met with the question, well, what would happen if someone were to—an organ were available and you were told that that organ is going to cost you $500 and then you find out that someone else from Kansas City has come in and said that they will pay $1,000 for that organ and we need it right away. You then get into some form of a bidding war, and the question is, where does that kind of thing stop?

Mr. **Dobrovitz**. You are asking me? I am not sure. I don't know. I am sure if you are talking $500 or $1,000, I'd be in the bidding for a while there. As it got higher, I don't know.

I think the real point is, though, from my perspective—and I can well appreciate other people who are very adapted to hemodialysis and are very comfortable with it and can live with that—for me it was a very difficult process. I was on dialysis for 8 years, and in my case I had to have my two kidneys removed before I could be eligible for a transplant.

And knowing that that was such a—in most cases considered medically a much more difficult operation than receiving the kidney itself, much more physically—and it was—it took me about 8 years to get up the nerve to have that first operation.

But the waiting period, that 3-month period that I went through, if that had dragged on much longer, I would have—I think I would have started to look because it's—I don't think there is any way you can really describe that feeling of, you just don't know.

You don't—I was engaged to be married at that time and our wedding plans were a day-to-day kind of thing because if I hadn't received the call when I did, so much for the band and the reception hall and all those kinds of things, and it really drove home that whole point about the transitive nature of how life had become. I don't—that's not a way I'd want to live for an extended period of time.

Mrs. SCHNEIDER. But it is also interesting to note that your desperation could have also been exploited because you had written I guess an editorial where you said that you would be willing to pay for a kidney, and I think that that is something else to take into consideration, the possibilities of exploitation there.

Mr. DOBROVITZ. Sure.

Mrs. SCHNEIDER. Dr. Newmann, has your organization taken any formalized stands or positions against the commercial sale of human organs?

Dr. NEWMANN. Yes. At our annual meeting just a few weeks ago we opposed the sale of human organs. As I pointed out, we did suggest that out-of-pocket expenses and lost wages should not—if they are paid for should not be considered illegal, but we are against the sale.

Mrs. SCHNEIDER. Does your organization have—and I regret that I was not able to hear your testimony. I had another markup going on, so I had to run out of here.

Does your organization have some type of proposal or organized scheme as to how we can increase the supply of organs?

Dr. NEWMANN. Yes. We have—are very much in support of Congressman Gore's bill, which suggests the national transplant registry, and we feel that the supply could be improved with increased funds for education of both the public and the medical profession. There certainly are enough kidneys around. It's just that they are not being retrieved.

Mrs. SCHNEIDER. And you think this legislation is the way to solve that problem?

Dr. NEWMANN. Yes. The one thing I wanted to mention—and the physicians can speak to this better than I—the present system is not a failure. As you know, something like 10,000 people are on waiting lists, and this year alone about 6,000 of those will be transplanted, so we have got almost 50,000 on dialysis who aren't on those lists yet, like myself, who are waiting for more improvements because we are doing fine.

I think it's terribly important for the physicians to point out that of those on the lists, what percentage of those are highly sensitized against organ transplants because the more blood you receive—and it's all on a case-by-case basis—the more antibodies your body produces, such that there are numbers of patients—and I don't know what the numbers are—on those waiting lists who might be able to accept 5 or 10 percent of the kidneys offered. So, even if the supply increased twofold or threefold, many of those currently waiting would not receive kidneys.

Mr. **Gore**. Will my colleague yield?

Mrs. **Schneider**. Yes.

Mr. **Gore**. We had testimony on that Monday, and the best estimates we can come up with are that at present about 10 percent of those Americans on dialysis are on the transplant list. If all of those who could be transplanted and arguably should be, were on the list, the figure would be about three times as high, or 30 percent. Seventy percent of those on dialysis probably should not be candidates for transplants, largely because they have become sensitized; that is, they have produced within their bodies antibodies that make rejection extremely likely.

Now, Dr. Greifer may add more on this, if you have any quarrel with the figures I have just given.

Dr. **Greifer**. I have no quarrel, and I think that the use of the term by Dr. John Newmann about blood sensitizing, the sensitivity develops and there are a large group of patients who have become sensitized over the years and they are not available for transplantation.

The other aspect of it, sir, is that what has happened in the system is that the average age of the individual on dialysis has moved from approximately 40 to 60, and also now includes many different kinds of diseases than what was originally primary kidney disease.

Mr. **Gore**. If my colleague will yield a little bit further, Dr. Greifer, we heard very troubling testimony Monday that a lot of people who should be on the transplant list are not being listed because their doctors—in this case, nephrologists—are not that eager to surrender control of their patients to a specialty that will actively consider a transplant strategy as treatment for those patients.

Now, if the number on the transplant list should be three times as large as it is—and this doctor testified that that was one of the principal reasons why the number is so low—that is a pretty troubling statement. Would you care to comment on that?

Dr. **Greifer**. I think that that's been a statement made over a number of years, Congressman Gore, and which it has been very hard to verify. One of the reasons being is that the concept is that the doctor-patient discussions and whether or not the patient wishes to be transplanted is always a very difficult one to interpret, whether or not the doctor has influenced the patient or the patient has been influenced by the results in their particular area over a long period of time.

I do think that, like everything, it may be a small truth to the statement. I don't think there is a large truth to the statement. I think those individuals who wish to be transplanted are not being prevented from seeking or being involved in transplant programs.

Most that are around the country, the end-stage renal disease program network systems have very strong programs as far as interrelationships between the transplant program and the, quote, which is the one I am bringing up, is the satellite dialysis centers.

The biggest problem, really, sir, what has happened is that though the numbers have changed, what people don't take into consideration is the state of the art change. People are still in their minds in the seventies and we are really in the eighties.

An individual who has severe hypertension, and individuals who have coronary artery disease, and individuals with diabetes who originally were not great transplant candidates and are in these units, represent close to 50 percent of all the patients now on dialysis.

What is happening is that with the state of the art improving, more and more patients with diabetes are being transplanted. So, I think you are going to see a change, and that statement will not hold up in the future.

Mr. GORE. I will come back to this on my own time.

Mrs. SCHNEIDER. No further questions.

Mr. GORE. Well, let me ask you, Dr. Newmann, then, what have you found among members of your organization?

Dr. NEWMANN. Well, we have found very few complaints by patients suggesting that their doctors are preventing them from opting for transplantation. That is not something that is very common at all.

Mr. GORE. Well, the statement Monday was not focused on preventing patients——

Dr. NEWMANN. Discouraging?

Mr. GORE. No, just not making them aware of this strategy and not recommending it in circumstances where it would clearly be indicated.

Dr. NEWMANN. Well, again our organization is primarily made up of patients, and we do all we can to educate our membership of all of the modalities. And anyone who reads our magazine, which comes out quarterly, will see that transplantation is a readily discussed issue.

I would be very surprised if that's a major deterrent. I think Dr. Greifer is correct in saying that the experience of the seventies was very bad for many people, and I think patients who are doing well on other therapies are more conservative.

I did want to mention one thing, and that is that the public may have an inappropriate image in terms of kidney transplantation dialysis of people dying waiting for kidneys. It's been my impression that the transplantation that goes on in this country does select those who are medically in greater need and are acceptable as recipients before people like ourselves, who were able to tolerate dialysis, even with its difficulties.

So, there is a real question as to what the appropriate numbers are as to the lack of supply meeting demand at this point.

Mr. GORE. Mr. Dobrovitz.

Mr. DOBROVITZ. One point I wanted to make, though, from my own personal experience. I don't know about individual doctors and what they do, but I know in my case there was no information given to me about the availability of cyclosporin in other medical centers around the country. I found that information out myself and contacted the University of Pittsburgh on my own.

There was no medical personnel in Rochester telling me that this was an option available and I might want to talk with them. I did that myself and subsequently got the ball rolling for myself at Pittsburgh. And because of the publicity that was generated through my operation, several more patients in Rochester now have gone to Pittsburgh because cyclosporin at the time was not available in Rochester.

Mr. **Gore**. Well, it just seems to me that the physician in charge of your dialysis treatment, as a matter of normal course, should have reviewed with you the options available and made you aware of what you could do, but you are telling me that didn't happen?

Mr. **Dobrovitz**. Well, I should also put that in the context that I was in a self-care dialysis unit where the philosophy is more the patient takes care of a major part of his own treatment in terms of setting up his dialysis machine and handling his treatments. So, there is maybe less of an interrelationship between the doctor and patient and, in a sense, the patient initiates that more frequently.

But still, it was a case where I work in a TV newsroom and I happened to be ripping the Associated Press wire machine one day and saw the article about cyclosporin, and that was how I found out about it.

Mr. **Gore**. Is that right?

Let me—yes, Mrs. Engebretsen? Turn that microphone around there.

Ms. **Engebretsen**. One of the things that concerns me very much about the legality of selling human organs is how this is going to affect the donor program. Now, I haven't got any solutions to this but I would like to just share with you something that happened last week.

It was very late at night, and I received a phone call. At first I thought the caller was inebriated. It was a man obviously very grieving. His child, my daughter's age, had died and he said, "Lady, you've missed your chance." I said, "Excuse me. What are you referring to?" This was very late at night and I had no idea why he called.

He said:

> My child died today. I saw you on national television. My daughter is the same size. I don't know if the blood group would match, but I tried to contact you. I called lots and lots of doctors to find out who you were and how I could sell you my child's liver. Well, it took too long. They couldn't find you, and it's too late now.

Now, this really bothers me because I wonder how many other people would wait until it is too late because they are trying to gain money for their child's organs. I said I felt very sorry for him. He had not only lost his child, but he had lost a chance to give another child life. How many times will this happen? This may be a very extreme case, but it is possible.

Thank you.

Mr. **Gore**. Well, thank you. That's a strong and powerful point. And you've made the point before that in circumstances such as those, that you find the prospect of buying and selling human organs is even worse in the case of buying and selling kidneys, because it is a vital organ and the only time when such haggling over price would take place is in the time of grief immediately following a child's death. It's just difficult to imagine two sets of parents, one grieving, the other anxious.

Ms. **Engebretsen**. Well, who would get the first chance to bid at that organ? The child who needs it the most or the parent with the most money?

Mr. **Gore**. Well, maybe the best response is the one you offered earlier. It's just wrong.

Ms. **Engebretsen**. It is very hard to defend that. You can't—it's the same as defending your religion. You just feel it's wrong. It offends your sense of right and wrong. It's not moral.

Mr. **Gore**. Let me call on my colleague, Congressman Volkmer.

Mr. **Volkmer**. No questions.

Mr. **Gore**. All right, fine.

Dr. Greifer, you wanted to make a comment?

Dr. **Greifer**. I think, again, going back to your original point, I am in charge of a children and adolescents kidney program and every individual is taught and it is discussed with them up front about transplantation.

Interesting enough, a number of young people going off to college opt to continue dialysis for the point of view of feeling that they are comfortable with it and, even though they have full knowledge of the transplant program, will not opt for a transplant for a number of years.

I think that that becomes an individual choice. We use the term now "renal replacement therapy" and which gives the option of two forms and gives the person the obvious right to decide which one they want.

The other thing, Congressman, is a question that was brought up about the availability of experimental drugs. This comes into a whole aspect of patients going to look for particular centers using experimental drugs that have not yet been approved by the Federal Drug Administration, nor have been proven scientifically, nor have papers been published at that point.

And it becomes a very big issue for the individual physician. Do they advise the patient to go for an experimental situation at that point? You always feel bad in retrospect if it worked out. If it didn't work out, you were right. Thalidomide is always the point, but the truth is if it didn't work out we would be in trouble.

Mr. **Gore**. Well, yes, with all due respect, I think the more pertinent comment is the one that you made earlier, when you said that there is an understandable human failure to recognize the great progress that has been made and with survival rates as high as they are, and it has happened so quickly, a lot of doctors really haven't realized how the odds have changed. Hopefully, the process of education will continue and be accelerated.

I appreciate your kind statements about the legislation, incidentally, and the national center. Dr. Newmann, I appreciate your organization's endorsement of the bill. And let me report to all of you that the Health Subcommittee passed the bill just yesterday and the full Commerce Committee will probably take it up next week and we will see whether it can pass before the adjournment time or not.

Mr. Dobrovitz, you wanted to make another comment?

Mr. **Dobrovitz**. Just one quick one, before you wrapped it up here.

I know both the doctor and I mentioned today the whole question of the presumed organ donor——

Mr. **Gore**. Yes, yes.

Mr. DOBROVITZ [continuing]. Plan. I guess it is my understanding that as it stands right now the legislation currently on the floor or to be put on the floor will not deal with that.

Mr. GORE. It does not include that.

Mr. DOBROVITZ. And you said something to us earlier that you just felt that the public wasn't ready for that yet. Is there any way for the public to voice its opinion? Is there any way through the ballot box or through a piece of legislation that the public can get to their representatives and have their opinion be felt?

Mr. GORE. Well, perhaps so. And as I said before, maybe I have misjudged the extent to which Americans would be willing to go to such a system. I know that there are some groups that would have a strong religious objection to this.

Mr. DOBROVITZ. But isn't that met in terms of——

Mr. GORE. Presumably opting out would satisfy that, but maybe that is a subject for another hearing. I will—I'll actively explore that issue and reconsider my own earlier judgment that this was not something that is politically doable. But I appreciate your comment.

One other thing. You said something that was—in your statement—that was intriguing to me. You said that the worst time you experienced in your own personal life was the few months while you were on the list waiting for the telephone to ring. I guess you had to stay pretty close by that phone, didn't you?

Mr. DOBROVITZ. Pretty much. I carried a beeper, as well. In my job I do a lot of traveling, and to run around the State doing assignment work, I had to keep in—the people who were involved in the program had to know where I was at all times.

Mr. GORE. OK.

Well, let me thank this first panel. We are going to move on to our second panel.

Mrs. Engebretsen, let me give you special good wishes and prayers for Trine. I hope that things work out well for you, and thank you again for your courage in coming here.

Ms. ENGEBRETSEN. Thank you very much, Congressman.

Mr. GORE. Thank you to all the witnesses on this panel. We appreciate your assistance.

Let me call our next panel to the witness table: Dr. Marvin Brams from the Department of Urban Affairs and Public Policy at the University of Delaware; Dr. Barry Jacobs from Reston, Va.—I am told that Dr. Jacobs hasn't arrived yet—and Dr. Oscar Salvatierra, with the American Society of Transplant Surgeons, University of California in San Francisco.

I'd like to welcome all of you. We are told that Dr. Jacobs has left his office and is en route, so we will ask him to join you at the witness table when he arrives.

We will begin, Dr. Brams, with you. We appreciate your presence. Without objection, the entire text of your prepared statement will be included in the record, and we invite you to proceed.

STATEMENTS OF MARVIN BRAMS, M.D., COLLEGE OF URBAN AFFAIRS AND PUBLIC POLICY, UNIVERSITY OF DELAWARE, NEWARK, DEL.; H. BARRY JACOBS, M.D., MEDICAL DIRECTOR, INTERNATIONAL KIDNEY EXCHANGE, LTD., RESTON, VA.; AND OSCAR SALVATIERRA, JR., M.D., PRESIDENT, AMERICAN SOCIETY OF TRANSPLANT SURGEONS

Dr. **Brams**. Currently there is a well-established altruistic system for making transplantable organs available to those who need them. Individuals relinquish organs to be removed upon their death or, in some cases, during their life without financial compensation.

The existing altruistic system of organ procurement and distribution is supported philosophically and administratively by powerful organizations such as the American Kidney Fund and the National Eye Institute.

While an altruistic system for organ transfer appeals to the noblest qualities of human beings, the unpleasant documented fact is that the system has not produced and is not likely to produce either in the short term or in the long term an adequate supply of certain organs for transplant.

For example, thousands of people presently on dialysis for renal failure await kidneys that they may never receive, and there also exists a serious shortage of corneas needed by blind persons.

This shortage of transplantable organs under the altruistic system can be attributed primaily to two causes: one, the public's lack of knowledge about the donor program; and two, an unwillingness by many persons to relinquish an organ voluntarily even when the facts are known.

One solution to this problem is statutory authorization of the sale of transplantable human organs. Commonsense, backed by extensive data on the relationship between economics and human behavior, suggests that many persons who would not donate their organs altruistically might sell those organs for a price.

Supplementing the current altruistic system with a commercial market system would present people with a new incentive to relinquish their organs, to be removed after death or perhaps even during their life. This combined altruistic and market system of organ procurement and distribution would substantially alleviate the current organ shortage.

What is the rationale for a statutory approach? The most significant aid to establishing this combined altruistic and market system of organ transfer would be the enactment of State laws authorizing the use of such a system, making it clear that the sale of human organs is lawful.

Why advocate a statutory approach? Four reasons:

First, it appears that in some States new legislation may be needed in order to protect parties involved in organ sale from any possibility of criminal liability for their actions. A sampling of State laws reveals that at least some States have statutes which might prohibit certain types of organ sale that are proposed in this solution.

The second reason: Because the Uniform Anatomical Gift Act authorizes gifts of organs but is silent concerning sale of organs, it may give the impression that such sale is unlawful. This view is erroneous. A statute clearly dispelling any notion of illegality, whether that notion was solidly grounded or not, would help the proposed system to flourish.

The third reason for the statutory approach: The introduction of an altruistic market system of organ transfer could be chaotic and perhaps injurious to the parties involved without a statute setting forth clear, consistent procedures for organ sale.

Fourth reason: Passage of a thoughtful and progressive statute might foster the change in social attitudes necessary to widespread acceptance and effective implementation of a proposed statutory system.

Development of a commercial market in human organs to supplement the existing altruistic system might, in addition to producing more donors, have two salutary side effects:

First, if the sale of organs were restricted to organs removed only after the donor had died, the larger supply generated from deceased donors through the market system might reduce the need for organ removal from living donors, obviously an important consideration. Surely both society in general and the medical profession in particular would have less objection to commerce in human organs if it were limited to deceased donors and if it reduced the need for altruistic transplants from the living.

Second, the introduction of a market system might raise the success rate of organ transplants. The larger supply of organs under a market system would enhance the possibility of obtaining organs which have less probability of being rejected.

What are the objections to a combined altruistic and market system? One problem that might arise upon the introduction of a combined altruistic market system of organ transfer is that many persons who formerly would have relinquished organs altruistically would no longer do so given the opportunity to relinquish organs in return for financial compensation. Nevertheless, a decrease in the supply of free organs seems a reasonable price to pay for an overall increase in the availability of organs.

Another possible objection is the inability of some potential donees to pay. What if a potential donee cannot afford to buy an organ? Of course, this problem of inability to pay is endemic to our entire system of health care delivery. Some donees might be unable to obtain the necessary funds from any source and, therefore, might require some assistance in this regard.

Organs for such donees might be supplied by altruistic persons, but even if they were not, it would be an absurd social policy to dismiss a market system capable of increasing the availability of needed organs simply because some cannot obtain the funds necessary to purchase them. We do not deny other forms of health care to persons who can't afford them simply because other persons can. We simply help those who cannot.

Another objection is that this system might produce a possible increase in inferior or diseased organs. However, objections to organ sale based on the argument that donors in need of money might lie about their health and that, as a result, there would be an increase in the number of inferior or diseased organs cannot be discounted but, of course, we do have such things as careful physical examination of a donor prior to organ removal and of the organ itself after removal to minimize this risk.

What are the ethical objections to an altruistic and market system? Current social norms and medical customs bear some hostility toward a market system in human organs. Selling or buying organs for money is regarded by many persons as unethical. This negative view should be reexamined for three reasons.

First, a strong argument can be made that if a mixed altruistic market system of organ transfer does indeed increase the availability of needed organs, it is ethically superior, not inferior, to a purely altruistic system in that it benefits a greater number of persons, while causing little or no harm to a significant minority.

Second, one who relinquishes an organ for money may well have an altruistic motive; for example, to acquire income to provide himself and his family with advantages he could not otherwise obtain. Love can be a motivating force behind such a transaction.

Third, we must remember that other necessary commodities, such as food, shelter, and medication, are currently supplied primarily through a market system with relatively few ethical objections being raised. Why should we as a society view the sale of human organs much differently?

Perhaps the market system should be restricted to the selling of organs to be removed only upon one's death, and if that worked, perhaps there would be no need to extend commercial markets to the living.

How would such a system get started, a statutory system that permitted commercial sale in organs, either for both deceased and living donors or simply for deceased?

First, this system could be introduced on an experimental basis in a single State.

Second, even if commerce in human organs were authorized by law, such commerce could hardly flourish and might never begin without a change in medical ethics regarding the selling of organs. The dominant position of the medical profession, at least today, as I understand it, is that it is considered unethical for surgeons to install a purchased organ. They can install one altruistically given, but not a purchased organ.

My closing comment: Perhaps an ideal society could rely solely on altruism to provide sufficient organs for transplant and could eschew commerce in human organs. But to cling to an ideal which condemns some people to death or suffering is a high price to pay for idealism. Those who insist upon the ethical superiority of a totally altruistic system impose heavy costs on those patients who could benefit from the pragmatic, efficient and immediate solutions that are offered by a combined altruistic and market system.

Mr. GORE. Thank you for your testimony. We will hold off on questions until the other panelists have made their statements.

I would like to call now on Dr. Barry Jacobs of Reston, Va., whose proposal to buy and sell human organs was not the first to be made, but the first that attracted widespread attention. We appreciate your willingness to come and help us to explore the issues surrounding this proposal, Dr. Jacobs.

Without objection, the entire text of your prepared statement will be put into the record. If you want to present it, we invite you to do so. If you care to summarize any portion of it, feel free to do that. Either way, it is up to you.

Dr. Jacobs. Well, thanks. I don't read prepared texts.

The first thing I want to make—point is that I think you ought to provide for parking. I drove around outside for 30 minutes trying to—and finally left it on the Ellipse somewhere.

I think Dr. Brams' last statement about the heavy costs on the suffering patients is well taken. I mean, those are the only people that are involved here, the 70,000 Americans that are chained and, as you call it, dehumanized. You call it dehumanized for other reasons, but I think that the person hooked to a kidney machine is dehumanized, psychologically and physically, and the family is dehumanized and destroyed because of it. So, those are the 70,000 dehumanized Americans we are talking about.

Second, I don't buy and sell kidneys. I only made a proposal to set up a brokering service so that the individual who wants to sell a kidney could be put in contact with the one that wants to buy the kidney.

I didn't hear what Dr. Brams said at the beginning. I don't know Dr. Brams. But he talked about, again, the heavy cost on the suffering patients. There is also a heavy cost on the taxpayers. Right now the dialysis program is about more than $2 billion a year cost to the taxpayers, who elected you, and I think those taxpayers ought to be able to share some of that relief of suffering.

So, if an individual wants to sell a kidney, it doesn't cost the Government anything. And if somebody else wants to buy a kidney, that doesn't cost the Government anything. But it ends up saving the Government. If 70,000 Americans end up with kidney transplants, it will save the Government billions of dollars a year.

Right now the cost of keeping a person alive, which the Government is paying for, on dialysis, it runs around $25,000 or $30,000 a year. And the cost of the kidney transplant operation—not the cost of the kidney, but the actual surgery, to remove the kidney from the donor, whether it be the brain dead cadaver, so to speak, or the live healthy—is being paid by the Government. They pay about $8,000 for that, and they pay the cost of the transplant operation.

So, in essence the cost of 1 year's dialysis is equal to the cost of the transplant surgery, the removal from the donor and the implantation into the body of the recipient. And since with the new drug cyclosporin, that kidney will last, a good 80 percent or more, survival for over 5 years, you're talking about basically 4 free years, from $100,000 to $140,000 savings per person who is transplanted.

The so-called altruistic system we have, I mean, look, it's been a dismal failure. It hasn't worked for years. Last year there were about 5,500 operations. About 5,000 of them were from the brain damaged individuals, and since most of them have two kidneys, we will talk about 2,200 or 2,500 people that have given up kidneys, of about 22,000, according to your quotes, Dr. Gore—Mr. Gore, about 22,000 that could have given them up.

Now, when a person is lying in a hospital on a respirator, there have been very effective regional organizations. For years they have transplant coordinators who come to the scene, beg doctors, beg family members to have the loved one lying there brain dead, kept alive, breathing on a machine to give up a kidney, and most of them refuse. They don't know what the wishes of the potential donor are, or for whatever reason they refuse.

So, the so-called altruistic system has been a dismal failure. A bigger supercomputer linking up the computers that now exist which are already linked together, maybe it will improve the matching possibly by a couple of percent, but that won't make a dent in the bucket.

And I remember when I was before Waxman's committee a few weeks ago, if you remember, there was—Dr. Starzl was there. And Dr. Stanzel, he was exhausted, working all night long, doing transplants and so on, and he came and testified. He got to say a very interesting point. He felt that the law that you are trying to propose is fine except he wanted to—except for one part.

He felt, according to what I recall of his testimony, that the prohibition on the sale of an organ, he wanted that taken out of the law, and he was cut off during his testimony, and I think that was wrong, for him to be cut off. I think what he had to say, as the most prominent transplant surgeon in the country, is accurate.

You talk about the marketplace——

Mr. Gore. Let me interrupt you there. His view was that he agreed with the prohibition on buying and selling of human organs.

Dr. Jacobs. But he didn't want it to be illegal in the law.

Mr. Gore. No, no, no. He recommended that it be pursued in a separate law so as not to jeopardize the passage of the rest of the law that—as it stands. He is in favor of both parts of the law, and my judgment is that both of them can pass together.

Dr. Jacobs. But I disagree with your perception of what he said, and I think he should have been allowed to speak further on the point, at which point he was cut off. He was cut off.

Mr. Gore. Well, I spoke with him and he did say that.

Dr. Jacobs. OK, well, that is fine, but what he said in public on the record, he was cut off at the point of his—I thought a critical point of his testimony for what this hearing is about today.

All I can say is that, you know, those 70,000—I don't know if you are familiar with patients on kidney dialysis machines. I mean, you probably are now. But they're the ones that are involved here, not you. I mean, you know, in Russia it is interesting. You know, the government owns your organ when you are dead. They have no transplant problems. I have also been told that they market organs from India and other countries.

The point is, in Russia they don't have a problem. The governments owns, you know, you have no choice. If you are in Russia and you die and you are on a respirator, you have no choice, your family has no choice, as far as I know, as far as taking away an organ.

In this country you want to propose a similar thing but to the reverse. You want to prevent people from doing with their bodies what healthy, informed adults—I'm not talking about children now, we are talking about consenting adults—want to do after they have to go through the medical system. They have to be examined physically, they have to be tested for all the appropriate diseases that exist and so on.

You know, it is safer to transplant an organ from a healthy living donor than it is to take it from a brain dead individual lying on a respirator because as the days and hours pass the chance of infection setting in into their kidney rises, so it is healthier to take it and safer to take it from a healthy living donor.

And second, we are talking about an elective situation. We are not talking about an emergency thing where you have only a few days to get the kidney out. We are talking about a healthy person who has been evaluated psychologically. I think Mr. Volkmer asked me, from Waxman's committee, to put in writing about psychological clearances.

Dr. Salvatierra—I still don't know how you pronounce your name—but I think personally he's got an inherent conflict. I will put it tastefully. He's willing to operate, or his group is willing to operate, and take a kidney out of a mother and give it to a son and take a kidney out of a cousin or uncle or brother and sister and give it to another member of the family for love when that kidney has the same 80-percent chance of survival as a well-matched—I am talking about well-matched—stranger, healthy stranger's kidney.

The motivation is not the important factor. You know, there are a lot of psychologically disturbed family members that out of guilt and similar—you know, "My God, I better do it. The family will start talking, and it's your sister, it's your brother. What are you going to do about it?" And they give up a kidney.

And if the kidney survives, that's fine. But if that kidney fails—and it has a 20-percent chance or so of failing—and if that kidney fails, you don't know the absolute psychological disasters that can befall such a person. I don't know what testing they do to be sure that such a person is psychologically healthy. But the stranger and the loved one both are under pressures. One may be under emotional pressure; the other may be under financial pressure.

But the psychological evaluations before they are ever touched and the entire system they have to go through in this country, which is having a physical examination by their own family doctor who will counsel them, by another physician before they even get into the hospital, by physical exam and blood tests and everything being done when they get into the hospital, and the clearances by the anesthesiologists and the clearance by the transplant surgeon and the doctor who is going to do a nephrectomy and the hospital personnel, you are talking about a whole chain of protections we already have in our system. No one is going to take someone's kidney out on a back table somewhere and sell it off on the marketplace. We are talking about a kidney that has to be removed in a hospital environment under all the State laws that now exist.

The Joint Commission on Accreditation of Hospitals and the American Hospital Association inspects hospitals and they certify hospitals. Our hospital system is more regulated than anything you could imagine. There is more protection and legal protections for informed consent built into the system civilly and criminally now than you can imagine. There are more protections for anyone who is going to walk into a hospital to give up a kidney or have any operation being done.

So, this so-called law I think is a fraud. I think the people now are protected. If someone wants to sell a kidney, I think it is his right. If somebody wants to purchase a kidney, it's their right. And we are not talking about depriving the indigent person of a kidney. They are now on a waiting list. They are waiting for the brain dead cadaver kidney to come available. Everybody has equal access. The best match gets it.

Well, if you can take half of those people off that waiting list because they can afford out of their own pocket to pay for a kidney, the Government is still going to pay for the operation and save billions of dollars on the cost to the taxpayers, your taxpayers, people who voted for you, to save billions of dollars of money; at the same time allow those who can afford—we are still in a capitalistic society here. Those that can afford it or the families that can afford it to purchase a kidney, that's a private transaction between two consenting adults. They get those people off of the waiting list, so instead of having let's say 10,000 or 20,000 people on the waiting list you have half as many for the same limited number of kidneys. So, their chance of getting a kidney is now two or three times better than it would have been. So, the indigent is benefited.

And there are some programs we can set up, any brokerage fees that will come in will be used to fully cover the cost of the kidney for those that can't afford the kidney, so we are talking about a system for all the Americans, including those that are dehumanized on kidney transplant machines.

[The prepared statement of Dr. Jacobs follows:]

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The voluntary organ donor program in this country is a dismal failure. Too many citizens -- children, women and men -- anxiously await the health-sustaining and life-saving kidney which they will never receive. Not under the current donor program which offers neither incentive nor motivation for people to give up one of their kidneys to a stranger. There is no stronger motivation than a monetary one. There are two ways in which our government can go about relieving the endless wait of 70,000 Americans -- an often unfulfilled wait for a life-saving kidney, and save $2 billion per year (the cost of dialysis).

One of these options involves the establishment of a donor bank whereby any healthy citizen can "will" their kidneys, for removal after their death, to a national kidney bank. If the organs can be used, the government can then financially compensate the deceased donor's family, as per the donor's wishes. A match would then be made between the donor's kidney and someone awaiting a kidney. Priority would be given to length of waiting time, quality of the match and medical necessity, regardless of social or financial status on the part of the recipient.

The government would fund the medical costs involved -- at a considerable savings over even one year of dialysis for a kidney patient today. Since 80% of transplanted kidneys will function for more than five years, each additional kidney transplant will save $142,000 over five years. For every thousand dollars used to purchase a kidney, the government will save $15,000 or more in the cost of dialysis. This concept is really no different from the Lion's Eye Bank or the annual Red Cross Blood Drive. The donor makes the rational decision to donate his kidneys, or eyes, before death, and, in so doing, helps not only his own family, which received a monetary "insurance" benefit, but two kidney patients who otherwise are doomed to an existence of living on a dialysis machine.

The second option is for the government to fund a program whereby an informed and consenting adult kidney donor can be compensated for donating one kidney while still alive, and enjoy both the financial and spiritual rewards of helping an otherwise helpless and hopeless individual -- one handcuffed to a dehumanizing kidney dialysis machine. Because of shortages, kidney transplant operations help less than one out of ten patients. The majority of the 5,000 kidneys transplanted each year come from only 2,200 brain-dead citizens whose families gave permission for organ removal from their loved one.

This program would not interfere with the limited source of brain-dead donor kidneys. In fact, this source would be augmented considerably.

There is a slight to moderate risk in transplanting cadaver kidneys due to a higher chance of infection caused by various methods used to keep the patient alive and ready for transplantation. All brain-dead respirator patients develop pneumonia (it is only a matter of days) and the infection risk to all their organs increases as each hour passes. Healthy donor kidneys are safer, more medical information about the donor is available and obtainable, more time is available to perform extensive testing, and the operations are electively scheduled.

God gave us two kidneys. We need only one-half of one kidney to live a normal healthy life. God also gave us the intelligence and ability to perform kidney transplantation operations. Some doctors raise the moral issue of risk when money is involved, but imply the risk is less for healthy close relatives donating a kidney. The risk to the donor is the same even though their motivation may be different. With a large enough "donor pool" a non-related donor's kidney has a very good chance of being a better match than, for example, a mother for her son.

The risk for serious injury or death is much less than one per thousand donors. It is the responsibility of the private physicians and operating surgeons to fully inform both donors and recipients of their respective risks, and to do everything necessary to minimize all risks.

The government should not have to fund the cost of organ transplantation. It is a well established principle of civil law that the one who causes the damage should be responsible for the cost of correcting the damage. Alcohol is the greatest cause of liver failure and a contributing cause of kidney failure. A slight increase in the tax on alcohol, borne by the users of alcohol who are subjected to the risk of alcohol, would pay for the cost of organs and for liver and kidney transplantation. Likewise, tobacco is a major cause of heart and lung disease, and a slight increase in the user tax for tobacco would pay for heart and lung transplantation operations and for the purchase price of those organs. This type of user tax is not unlike the tax for gasoline which is used to pay for construction and repair of roads.

In the final analysis, the kidney debate should be resolved by individual doctors and their patients; not by politicians.

H. Barry Jacobs, MD.
H. Barry Jacobs, M.D.
Medical Director

10/13/83

Mr. **Gore**. Since you spoke off the cuff, let me just ask you before going to our third witness, you are still—the system you are proposing, so we have it before us on the table, you are still contemplating bringing people from the Third World over here and paying them to have a kidney removed?

Dr. **Jacobs**. I am contemplating three things. The first thing is a monetary incentive program where our Government will allow people while they are healthy and alive to sign up for a system where if they should have an accident or a stroke or something, and they unfortunately turn out to be one of those 22,000 Americans a year that are on a respirator, their wishes will be known in advance that their loved ones will get kind of like an insurance policy, if their organs—we are talking about hearts, livers, kidneys, et cetera, if they are brain dead people. If their organs can be used, their will is known in advance. Their loved ones will get like an insurance policy if their organs can be used, so they will have made their will known. That's the first one.

The second one are healthy, living Americans who, while they are alive and fully, you know, checked out in our medical system we have now, could give up a kidney, if they wish.

And the third is if that source is not available—if there aren't enough Americans available to meet that source—I think there will be, but if there aren't—then we go outside the country. You say Third World. Well, let's talk about England, too. There are plenty of people all over this world who would be willing to sell a kidney.

The point is that they will be put through a system, hopefully operated upon in this country, if you don't make it illegal, where they have all the full protections of informed consent and all the proper protections in our country, so that whatever source is necessary to meet the need, if we don't make it with the healthy, living while they are alive signing up so if they are brain dead their organs can be used—and I think that may just solve the whole problem, but if that doesn't, to fill the gap in there we have healthy, living Americans giving up a kidney while they are healthy and alive.

And the risk of taking out one kidney is quite minimal. The American—National Kidney Foundation quotes the same thing, minimal risk. They are encouraging living, healthy, related people to give up a kidney. They will put the mother on the block. The stranger has the same risk as the mother.

And then if the gap isn't met there, then we are talking about going outside the country. If you make it illegal here, it will happen like abortions happened, what, 30 or 40 years ago. Those who can afford it and don't want to wait and have the chance of dying and suffering on a dialysis machine, they will go out of the country. It will be set up outside this country without all the safeguards we have in this country, so you basically are subjecting Americans—if you make it illegal and they want a kidney, and many can afford it, to go outside this country to hospitals and environments that are not as fully protected and not as safe and secure as we have in this country.

One thing that's happened, though, I think you ought to be aware of. The practical aspect of what's happened, where I don't even think you have to make it illegal, it's really an antitrust question.

According to Dr. Salvatierra's quotes in the newspaper, in the Los Angeles Times I just saw the other week, when Waxman was in California, there are three—and others, Dr. Terasaki, and others. There are three basically transplant organizations—[to the photographer] you want me to smile? There are three transplant—you are really annoying me. Thank you.

There are really three transplant organizations in this country of surgeons, and the International is one of the three, and apparently they have taken a position that they are against the buying and selling of kidneys. Well, that's their position and that is OK to take a position, but they have taken one step further, which is really a legal question, which I think is getting them into dutch civilly.

The position they took is that they are willing to and they threatened to expel any one of their members—they threatened—it's in the newspapers, the Los Angeles Times quoted them. Now, they have misquoted me a lot, so maybe they misquoted them, too. But if it's accurate—if it's accurate, then they've threatened to expel their members if they operate on a patient when an organ is for sale.

That, to me, is tortious interference in the business of anyone who is brokering organs, and it is also an antitrust question since they control all the transplantation doctors in this country who, in essence, control the hospitals. So, they have now set themselves up for an antitrust lawsuit.

Mr. Gore. OK, Dr. Jacobs. Your testimony obviously provokes a lot of questions which we will patiently hold until we have heard from the final member of the panel.

Dr. Oscar Salvatierra is president of the American Society of Transplant Surgeons. He is at the University of California in San Francisco.

Dr. Salvatierra, we are delighted and honored to have you testify here. We invite you to proceed.

Dr. Salvatierra. Mr. Chairman, members of the subcommittee, I am here today representing the American Society of Transplant Surgeons, which is the professional organization comprised of over 300 surgeons in the United States who specialize in transplanting organs, such as kidney, heart, heart-lung, liver, or pancreas.

The society appreciates your invitation to participate in these hearings, and we are anxious to share with you our views regarding recently publicized proposals to buy and sell kidneys from living unrelated donors through an organ broker for purposes of transplantation.

This is a very timely hearing since the field of transplantation has entered a new era characterized by substantial increases in the survival rates of a variety of transplantable organs. Precisely because of this brightened outlook for successful transplantation, there is an increasing need for organs, as more and more desperate patients, wanting to survive and live better lives, seek the benefits of transplantation.

The critical question before us today is whether the needs for organ transplantation can best be met by expanding and improving the current, voluntary, nationwide system for organ donation, or by allowing the concurrent commercial sale of human organs.

The American Society of Transplant Surgeons has recently surveyed the transplant programs in the United States, and they have expressed a desire for the strongest possible position against the commercial sale of human organs.

I would like to interject for the record that Dr. Starzl's position is that he himself is personally against the commercial sale of human organs and he does support legislation making it illegal to participate in this commercial venture.

There are four major problem areas that prompt our opposition to the commercial sale of human organs.

First, the proposal is morally wrong because body parts most likely to be harvested and marketed will most likely be those of the poor. We do not allow people to sell their bodies into slavery, so why should we permit them to sell body parts?

It is offensive to make a person's body into an object for purposes of economic gain. If organs were for commercial sale, the donor would be giving up an organ not because he or she was a suitable donor, as in living related kidney transplantation, but most likely simply for monetary gain.

Under a commercial program the "have nots" would become sources for the "haves" and thereby lose their dignity as human beings. A commercial program would discriminate against the poor, since it is the poor, or the individual with financial difficulties, who would most likely serve as a donor in this proposed commercial enterprise and risk his health. This risk may be high, as the poor often have other imposed health problems related to their poverty. And I should also mention that in the living related experience throughout the world there have already been 16 deaths.

In addition, since organs would probably go to the highest bidder, the individual who was poor, but had the same illness requiring transplantation, would be placed at a tremendous disadvantage regarding access to an organ transplant. Such an enterprise completely refutes a basic American belief that all our citizens have the right to equal access to health care. The allocation of lifesaving transplants on the basis of what the marketplace will bear is blatantly unfair to the poor, and medicine cannot morally allow itself to be used in such a fashion.

Second, there are some definite health risks to both the donor and recipient under a commercial program. The very extensive medical and psychological screening and education that is a very necessary part of living related kidney transplantation would be very difficult where kidneys are being sold for profit.

Donating a kidney is not comparable to donating a unit of blood. It entails a major operation from which serious physical or psychological complications might ensue, and it is not to be undertaken lightly, and I have already mentioned the 16 deaths.

Certainly a person can live normally with one kidney, or even part of one kidney, but there is a small risk that a problem may develop in the remaining kidney. Programs with living related transplantation follow their donors very closely for the remainder of their lives. The decision to use a relative's kidney is made only after very intensive evaluation of the risks and benefits involved.

In addition, the prospects of success with an organ from a living relative are generally better than those possible with an unrelated donor source. And in reference to a point made by a previous witness, at our center we do not go ahead with a living related transplant unless there is the prospect of success of 90 percent or greater.

In a commercialized venture, however, the donor may risk his or her health, or even life, out of desperation or ignorance and without better prospects of success for the recipient than if a cadaver kidney was used.

There is also the possibility that the recipient might be harmed because of the inadequate screening of the donor for a transmissible disease. Such a disease would later become manifest, particularly while the recipient is taking immunosuppressive medications following the transplant.

In the eagerness to receive money, a donor may not reveal all his past illnesses, nor may the organ broker be properly motivated to determine a potential donor's medical unsuitability. It is also conceivable that the donor may not know the nature of his past illnesses if he has not received medical care in the past. Certainly this may be the case with the poor.

An example of the potential problem is our historic experience with paid blood donors and the high incidence of hepatitis transmitted by these transfusions by paid blood donors. This problem has now been controlled by the use of volunteer blood donors.

In regards to the first two considerations described, the moral and health issues enumerated can only be compounded by the suggestion that people from other countries would be imported to serve as kidney donors for American patients with kidney failure.

Third, and very important, is the fact that the sale of kidneys from living unrelated donors could undermine our voluntary cadaver organ donor system, which depends on altruism and humanitarianism. It is well recognized that commercialism does repress the expression of altruism. We have primarily been talking about the sale of kidneys in that each person has two kidneys and can live with only one. With the commercial emphasis on live kidney donation, multiple cadaver organ donation could be discouraged. The public could easily assume that commercial programs would fulfill all transplant organ needs, even though the kidney is the only organ that can be removed from a living person.

This could have a devastating effect on the donation of important organs which are not paired, such as the heart and liver, and these vital organs can only be obtained from cadaver sources.

The giving of any organ provides a gift of life to one in need of that organ to save his or her life or to alleviate suffering but only when that donor no longer has the need for those vital organs—that is, at the time of death—and only because a grieving family agrees to the donation of those organs.

Fourth and last, it is contrary to the ethics of medicine to place an individual at risk when there is a viable, nonrisk alternative. Why remove kidneys from living unrelated human beings when we are currently utilizing only a small fraction of potentially available cadaver donors?

The deficiencies that we are currently experiencing in our voluntary organ donation system result primarily from an imbalance in the supply and demand for organ transplants. This, in turn, relates to the technological explosion and successes of organ transplantation which have outpaced the logistical considerations involved in organ donation.

Cadaver organ donation is an extremely complex process involving multiple levels of decisionmaking, organization, and care, beginning with the identification of the potential donor in a community hospital and followed by multiple intervening processes, such as surgical procurement, organ preservation, tissue typing, et cetera, until the eventual transplantation of the donated organ takes place.

The voluntary organ donation system, although presently outpaced by the technological advances in transplantation, has provided many individuals with successful transplants. The solution appears clear regarding the choice of alternatives to correct the current shortage of donor organs. We must improve and expand our current voluntary organ donor system.

It is our sincere hope and we are confident that legislation recently introduced by you, Mr. Gore, and by Mr. Waxman, Mr. Luken, and Mr. Skeen, will further promote organ donation and improve the efficiency and effectiveness of our organ distribution systems.

We are also pleased that Senators Kennedy, Heinz, Metzenbaum, and Reigle introduced a similar bill, S. 2018, on October 27 and that Senators Tsongas, Pell, and Symms introduced a Senate resolution condemning the sale of human organs.

We cannot, therefore, conceive of any logical reason to either supplement or replace our present voluntary organ donor system by a commercial system to meet the increased needs for organ donation.

The ethical tenet upon which all medical practice is based is "Do good and, above all, do no harm." The goal of organ transplantation is alleviation of suffering and prolongation of meaningful life. Organ transplantation should not in any way involve exploitation of the poor, nor the treatment of human organs as mere commodities.

The American Society of Transplant Surgeons is so strongly opposed to the commercial sale of organs that it adopted a resolution along with the International Transplantation Society and the American Society of Transplant Physicians.

The resolution in part reads that these societies "* * *strongly condemn the recent scheme for the commercial purchase and sale of organs from living donors. This completely morally and ethically irresponsible proposal is rejected as abhorrent by members of these transplantation societies. Removal of organs and transplantations of organs obtained commercially will not be handled by any members of these transplantation societies," and yes, we will be expelling members who participate in these efforts.

Even though those committed to transplantations will not participate in such a scheme involving the commercial purchase and sale of organs, we must still recognize that this procedure may be carried out by others. If this is done, it would be extremely detrimental to the voluntary organ donor system and thus jeopardize the future of many patients awaiting transplantation.

The risks are too great not to have appropriate legislation. We therefore strongly support title III of H.R. 4080 and S. 2018, which would make it unlawful to engage in plans for the sale of human organs. The existence of such proposals, however abhorrent, very clearly underscores our present problems with shortage of organs for transplantation. This, therefore, lends additional support to the other provisions espoused in H.R. 4080 and S. 2018, which would enhance the voluntary organ donation system.

A significant part of the tragedy with the proposal for the commercial *buying and selling of organs* is that it has misled the American people with false hopes. Organ transplant centers through the country have been beseiged by numerous calls and letters from people willing to sell their organs, with the hope that the income gained might provide solutions to some of their economic problems.

At our center at the University of California one individual offered to sell a kidney for $160,000. An example of a typical offer is a quote from the following letter. Quote, "I will sell one of my kidneys to the best offer over $50,000, plus all expenses. This is a firm offer."

It is easy to see how the possibility to sell an organ might provide an irresistible but misleading offer for an individual with severe financial problems, large debts, and no hope of immediate improvement or resolution. The sale of organs cannot be a viable solution to these problems.

Pivotal to all the problems that I have enumerated is the broker's fee, which has ranged—and there are different considerations—$5,000 is the most frequently quoted fee—for arranging the sale of a kidney, for merely putting a potential donor in contact, with which I would assume would be the highest bidding potential recipient and without any assumption of responsibility for the myriad potential problems that this act might ensue. This must never be allowed to happen.

In summary, Mr. Chairman, our society strongly opposes the commercial sale and purchase of organs. At the same time, it supports H.R. 4080 and S. 2018, which would make it illegal to engage in the commercial purchase of organs and which would also promote in a most expedient manner our voluntary organ donation system.

The answers to some of the questions posed by Mr. Dobrovitz and Mrs. Engebretsen would be answered by the passage of this legislation. Our ultimate and most important goal as espoused in these bills is to provide timely and successful organ transplantation for many of our citizens who need kidney, heart, heart-lung, liver or pancreas transplants.

Mr. Chairman, I want to express my sincere appreciation to all members of your committee for their interest and deep consciousness in this major public health issue, which impacts on the lives and welfare of many American citizens and their families.

Mr. GORE. Thank you very much for a very powerful statement, Dr. Salvatierra. I commend you and your society for your leader-ship on all of the issues surrounding transplantation. I appreciate the chance to work with you.

[The prepared statement of Dr. Salvatierra follows:]

TESTIMONY BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Washington, D.C.
November 9, 1983

Oscar Salvatierra, Jr., M.D.
President, American Society of Transplant Surgeons

Mr. Chairman, I am Oscar Salvatierra, M.D., Professor of Surgery and Urology, and Chief of the Transplant Service of the University of California, San Francisco. I am here today representing the American Society of Transplant Surgeons, which is the professional organization comprised of over 300 surgeons in the United States who specialize in transplanting organs such as kidney, heart, heart-lung, liver, or pancreas. The Society appreciates your invitation to participate in these hearings, and we are anxious to share with you our views regarding recently publicized proposals to buy and sell kidneys from living unrelated donors through an organ broker for purposes of transplantation.

This is a very timely hearing since the field of transplantation has entered a new era characterized by substantial increases in the survival rates for a variety of transplantable organs. Precisely because of this brightened outlook for successful transplantation, there is an increasing need for organs, as more and more desperate patients, wanting to survive and live better lives, seek the benefits of transplantation. The critical question before you today is whether the needs for organ transplantation can best be met by expanding and improving the current, voluntary, nationwide system for organ donation, or by allowing the concurrent commercial sale of human organs.

At the outset, Mr. Chairman, I can categorically state that transplant surgeons have been appalled with the recent proposals dealing with the sale of human organs. We want to clearly state our opposition to such practices and our intention to actively discourage such activities.

The American Society of Transplant Surgeons has recently surveyed the transplant programs in the United States, and they have expressed a desire for the strongest possible position against the commercial sale of human organs. We are totally opposed to the commercial buying and selling of organs, an idea which is morally repugnant and reprehensible, and in addition potentially unhealthy to both the donor and the recipient of the organ. We must not allow profiteers to exploit people who might be in a desperate economic situation, or who might not be carefully screened or provided with the necessary long term follow up.

There are four major areas we would like to review in regards to our opposition to the commercial sale of human organs.

First, the proposal is morally wrong because body parts most likely to be harvested and marketed will be those of the poor. We do not allow people to sell their bodies into slavery, so why should we permit them to sell body parts? It is offensive to make a person's body into an object for purposes of economic gain. If organs were for commercial sale, the donor would be giving up an organ not because he or she was a suitable donor as in living related kidney transplantation, but simply for monetary gain. Under a commercial program, the "have-nots" would become sources for the "haves" and thereby lose their dignity as human beings. A commercial program would discriminate against the poor, since it is the poor, or the individual with financial difficulties, who would most likely serve as a donor in this proposed commercial enterprise and risk his health. In addition, since organs would go to the highest bidder, the individual who was poor, but had the same illness requiring transplantation, would be placed at a tremendous disadvantage regarding access to an organ transplant. Such an enterprise completely refutes a basic American belief that all our citizens have the right to equal access to health care. The allocation of lifesaving transplants on the basis of what the marketplace will bear is blatantly unfair to the poor, and medicine cannot morally allow itself to be used in such a fashion.

Second, there are some definite health risks to both the donor and recipient under a commercial program. The extensive medical and psychological screening and education that is a necessary part of living related kidney transplantation would not be possible where kidneys are being sold for profit. Donating a kidney is not comparable to donating a unit of blood; it entails a major operation from which serious physical or psychological complications might ensue, and it is not to be undertaken lightly. Certainly a person can live normally with one kidney, or even part of one kidney; but there is a small risk that a problem may develop in the remaining kidney. Programs with living related transplantation follow their donors very closely for the remainder of their lives. The decision to use a relative's kidney is made only after intensive evaluation of the risks and benefits involved. In addition, the prospects of success with living related transplantation are generally better than those possible with an unrelated donor source. In a commercialized venture, however, the donor may risk his or her health out of desperation or ignorance, and without better prospects of success for the recipient than if a cadaver kidney was used.

There is also the possibility that the recipient might be harmed because of the inadequate screening of the donor for a transmissible disease. Such a disease would later become manifest, particularly while the recipient is taking immunosuppressive medications following the transplant. Certainly, in the eagerness to receive money, a donor may not reveal all his past illnesses nor may the organ broker be properly motivated to determine a potential donor's medical unsuitability. It is also conceivable that the donor may not know the nature of all past illnesses if he has not received medical care in the past. An example of the potential problem is our historic experience with paid blood donors and the high incidence of hepatitis transmitted by these transfusions. This problem has now been controlled by the use of volunteer blood donors.

In regards to the first two considerations described, the moral and health issues enumerated can only be compounded by the suggestion that people from Third World countries would be imported to serve as kidney donors for American patients with kidney failure.

Third, and very important, is the fact that the sale of kidneys from living unrelated donors could undermine our voluntary organ donor system, which depends on altruism and humanitarianism. It is well recognized that crass commercialism represses the expression of altruism. In the commercial sale of human organs we have primarily been talking about the sale of kidneys in that each person has two kidneys. However, this could have a devastating effect on donation of other organs which are not paired, such as the heart and the liver, and these other vital organs can only be obtained from actual cadaver sources. With the commercial emphasis on live kidney donation, multiple cadaver organ donation would be discouraged. The public could easily assume that commercial programs would fulfill transplant organ needs, even though the kidney is the only organ that can be removed from a living person. This would undermine our voluntary system of cadaver organ donation whether kidney, heart, heart-lung, liver or pancreas is involved. Indeed, the public is already confused and misled by the publicity surrounding the man who wished to sell not only a kidney but also one of his eyes. The giving of any organ provides a gift of life to one in need of the organ to save his or her life or to alleviate suffering, but only when that donor no longer has need for those vital organs, that is at the time of death, and only because a grieving family agrees to the donation of more than one organ so that the lives of several individuals may be sustained.

Fourth and lastly, it is impossible for a physician to ethically justify the removal of kidneys from living unrelated human beings when we are currently utilizing only a small fraction of potentially available cadaver donors. The deficiencies that we are currently experiencing in our voluntary organ donation system result primarily from an imbalance in the supply and demand for organ transplants. This in turn relates to the technological explosion and successes of organ transplantation which have outpaced the logistical considerations involved in organ donation. Cadaver organ donation is an extremely complex process involving multiple levels of decision-making, organization, and care, beginning with the identification of the potential donor in a community hospital, followed by multiple intervening processes such as surgical procurement, organ preservation, tissue typing, etc., until the eventual transplantation of the donated organs takes place. The voluntary organ donation system, although presently outpaced by the technological advances in transplantation, has in essence been good and has provided many individuals with successful transplants. Yet it is mandatory and extremely important to further improve and expand our current system. It is our sincere hope that legislation recently introduced by you, Mr. Gore, and Mr. Waxman, Mr. Luken and Mr. Skeen (H.R. 4080) will further promote organ donation and improve the efficiency and effectiveness of our organ distribution systems. We are also pleased that Senators Kennedy, Heinz, Metzenbaum and Riegle introduced a similar bill (S2018) on October 27, 1983, and that Senators Tsongas, Pell and Symms introduced a Senate Resolution condemning the sale of human organs. We cannot conceive of any logical reason to either supplement or replace our present voluntary organ donor system by a commercial system to meet the increased needs for organ donation.

The tenets upon which all medical practice is based is "primum non nocere" -- "First of all, do no harm." The goal of the transplantation of organs is alleviation of suffering and prolongation of meaningful life. The poor should not be exploited nor human organs treated as mere commodities.

The American Society of Transplant Surgeons is so strongly opposed to the commercial sale of organs that it adopted a resolution along with the International Transplantation Society and the American Society of Transplant Physicians. This resolution in part reads that these Societies: "strongly condemn the recent scheme for the commercial purchase and sale of organs from living donors. This completely morally and ethically irresponsible proposal is rejected as abhorent by all members of these transplantation societies. Removal of organs and transplantation of organs obtained commercially will not be handled by any member of these transplantation societies, and anyone doing so will be expelled." Even though those committed to transplantation will not participate in such a scheme involving the commercial purchase and selling of organs, we must still recognize that this procedure may be carried out by others. If this is done, it would be extremely detrimental to the voluntary organ donor system, and thus jeopardize the future of many patients awaiting transplantation. We therefore strongly support Title III of H.R. 4080 and S2018 which would make it unlawful to engage in plans for the sale of human organs. The existence of such proposals, however abhorent, very clearly underscores our present problems with shortage of organs for transplantation. This, therefore, lends additional support to the other provisions espoused in H.R. 4080 and S2018 which would enhance the voluntary organ donation system.

A significant part of the tragedy with the proposal for the commercial buying and selling of organs is that it has misled the American public with false hopes. Every organ transplant center in this country has been besieged by numerous calls and letters from people willing to sell their organs with the hope that the income gained might provide solutions to some of their economic problems. At our center at the University of California, San Francisco, one individual offered to sell a kidney for $160,000. An example of a typical offer is a quote from the following letter: "I will sell one of my kidneys to the best offer over $50,000 plus all expenses. This is a firm offer." It is easy to see how the possiblity to sell an organ might prove an irresistible, but misleading offer for an individual with severe financial problems, large debts, and no hope of immediate improvement or resolution. The sale of organs cannot be a viable solution to these problems.

Pivotal to all these problems that I have enumerated is the $5,000 broker's fee for arranging the sale of a kidney - for merely putting a potential donor in contact with the highest bidding potential recipient, and without any assumption of responsibility for the myriad potential problems that this act might create. This must never be allowed to happen.

In discussing the commercial sale of organs, it is worthy to note that not even one of the 480 patients awaiting a cadaver kidney transplant at my center has asked to buy an organ. I sincerely believe that this situation generally prevails throughout the country. For example, in testimony before the House Subcommittee on Health chaired by Representative Waxman in Los Angeles on Monday, October 31, child actor and dialysis patient Gary Coleman dramatically indicated, that despite his need and desire for a kidney transplant, he would never consider the purchase of a kidney.

Our examinations of proposals for the commercial purchase of organs for transplantation clearly underscore our present problems with shortage of organs for transplantation. These proposals only strengthen support not only for Title III of H.R. 4080 and S2018; but more importantly, they emphasize the need for the implementation of the other provisions of H.R. 4080 and S2018 which would promote organ donation and improve the efficiency and effectiveness of organ distribution systems.

In summary, Mr. Chairman, our Society strongly opposes the commercial sale and purchase of organs. At the same time it supports H.R. 4080 and S2018 which would make it illegal to engage in the commercial purchase of organs and which would also promote our voluntary organ donation system. Our ultimate and most important goal, as espoused in these bills, is to provide timely and successful organ transplantation for many of our citizens who need kidney, heart, heart-lung, liver, or pancreas transplants.

Mr. Chairman, I want to express my sincere appreciation to all members of your committee for their interest and deep consciousness in this major public health issue which impacts on the lives and welfare of many American citizens and their families.

Mr. GORE. Dr. Jacobs, you want to make a statement?

Dr. JACOBS. Yeah.

Mr. GORE. We are going to go to questions, but go ahead.

Dr. JACOBS. I think you—I think we ought to clarify certain things that Dr. Salvatierra said that are false and misleading. Many things he said are true and accurate, and I think they ought to be pointed out before you jump on the bandwagon that I think is going to get you into some problems.

He talks—and I am quoting him from what he just said. He said, "Living related is suitable." Those are suitable because they are living related. That is a moralistic judgment. There is no question about that. If there is a good match, then it is suitable. If it's a bad match, then it's not suitable.

If the pool is large enough, there is a chance of getting a living—the chance of finding a living, healthy stranger's kidney to match the person on dialysis for transplantation, can often be better than a close family member.

If you understand that the genes that go into a child come from one stranger, a mother, to a stranger, a father, so they are a mixture. The chance of having two brothers have the same genes, other than identical twins, is a mixed bag of genes of two strangers' kidneys going into his and two strangers' kidneys—genes going into another child, another sibling. It is a genetic pool. So, the only thing that is suitable is if the match is good. That's what is suitable. Not the moralistic judgment.

You got to understand something else, where he is coming from. His group is out to benefit from substantially large numbers of heart and liver and, hopefully, kidney transplants because the other part of the bill, the funding end of it—I haven't seen Dr. Salvatierra, or let's say the members of his organization, give up the Cadillacs and Mercedes for the poor in this country. I haven't seen them drop their fees to 10 percent of what they are ripping off the public for. I haven't seen them drop down their office charges for the indigents. Why should they? They are being paid by medicare. What the hell do they care about savings?

If you want to do something good around here, drop the cost of transplantation in half and drop the cost of dialysis in half. Then you will find out where the altruism comes from the physicians' end of it. It's a bunch of crap.

With regard to the other statements of his about the risk to the poor, a poor——

Mr. Gore. First of all, before you go on, let me say that I am personally familiar with many cases where surgeons' fees are not even charged for some of these operations. Dr. Shumway's group, for example, doesn't charge surgeons' fees. I am familiar with numerous cases around the country, particularly with the liver transplants, where the surgeons have said forget about——

Dr. Jacobs. Forget about it because they are not being paid by medicare right now, but when this bill comes to be law, they will be paid and then they will—you tell me Salvatierra doesn't get paid or his hospital because he probably—I don't know if he is on full-time staff or not, but the point is you tell me they have waived their fee when medicare is paying the bill? That is a fraud. Medicare doesn't pay the bill for hearts and Shumway does hearts and Starzl does livers.

Medicare doesn't pay the bill for livers, but though they do pay the bill for kidneys right now and they are hoping—they are hoping to God that—for the Bible Belt to God—hoping to God that the funding will come through for hearts and for livers because the university centers are the ones that are going to benefit the most. The smaller community hospitals will never see a penny of that money, nor will the doctors working at the smaller community hospitals. They may have an opportunity to do kidneys because that is a simple operation.

Mr. Gore. Well, first of all, you seem to be under the impression that the legislation would automatically provide for the funding——

Dr. Jacobs. Well, that's what's hoped.

Mr. Gore [continuing]. For these procedures.

Dr. Jacobs. That's what you are saying, to make it set up to go that direction.

Mr. Gore. Let's hope that the legislation will establish a more rational and integrated national system, and if the decisions are made on a more timely basis as to when a medical procedure is no longer experimental but has become viable, then it would be treated like other medical procedures.

But I wanted to come back to the first statement that you made, and I will give you—I know that you want to comment on this as well, Dr. Salvatierra. But you talked about the distinction between living related and living unrelated. I think there are two separate issues there. One is the match of the donors——

Dr. Jacobs. That's the key: match.

Mr. Gore [continuing]. And I think your statement that there is no difference between living related and living unrelated——

Dr. Jacobs. If you have a good match.

Mr. Gore [continuing]. Is a statement that some would argue with. But I think that the use of cyclosporin and better matching techniques can lead to matches from cadaver donors, as well as others that are very, very close. That question is arguable.

The more important point is that medical ethics requires that there be a health benefit for the assumption of a health risk.

Dr. Jacobs. You want to legislate medical ethics.

Mr. Gore. No, no, I am not. That is not my point.

Dr. Jacobs. Well, tell me what you are saying.

Mr. Gore. Well, if you will allow me to I will, Dr. Jacobs.

Dr. Jacobs. I am sorry.

Mr. Gore. If a living-related donor seeks to donate to a member of that person's family, conventional medical ethics concedes there to be a healthy benefit from that donation, because the donor is avoiding the trauma of seeing a family member suffer, possibly die——

Dr. Jacobs. And what happens with the kidney?

Mr. Gore [continuing]. And they have made that choice——

Dr. Jacobs. Correct.

Mr. Gore [continuing]. Voluntarily without monetary incentives being——

Dr. Jacobs. Don't use the word "voluntarily." Don't use the word "voluntarily" when the family members are beating on their head to do it.

Mr. Gore. Well, in most cases doctors have now devised rather extensive and elaborate procedures to insulate family members against such pressure. There is no doubt that you are correct that such pressure exists, but there are extensive procedures now to make absolutely certain that there is a truly voluntary choice, and there are ways for family members under such pressure to opt out at the last minute without any member of the family realizing that it was not a medical decision that led to the decision——

Dr. Jacobs. They give them a way out. They should give them a way out, yeah.

Mr. Gore. Well, they are given a way out, and family members don't even know the reason why if they choose not to do so. I might also add——

Dr. Jacobs. But the loved one knows.

Mr. Gore. No, they don't.

Dr. Jacobs. No, no, the one who is making the decision knows.

Mr. Gore. The person who makes the decision knows. That's right.

Dr. Jacobs. With the guilt attached to that.

Mr. Gore. Well, studies indicate that—followthrough studies on living related donors indicate that the psychological aftermath is extremely positive in an overwhelming majority——

Dr. Jacobs. When it works.

Mr. Gore [continuing]. Of the cases.

Dr. Jacobs. When it works, when the kidney in the recipient lives.

Mr. Gore. Dr. Salvatierra, can you respond to this comment?

Dr. Salvatierra. Yes, just to go over a couple of the comments, if you would permit me, that have been made.

I think in terms of surgical reimbursement for the nonkidney areas of transplantation, there is essentially no surgical reimbursement. For the kidney area of transplantation, the reimbursement for the procedure is about half of what it is for comparable procedures.

Dr. Jacobs. Well, how much is it? How many thousands of dollars do you get paid or does the doctor get paid?

Mr. GORE. Eighty percent of $3,800.

Dr. JACOBS. For a 1-hour operation. That's pretty good money, huh? It only takes an hour. How long does it take you to do the kidney transplant? Tell us, so we know. An hour in the operating room, 45 minutes, 2 hours?

Mr. GORE. Dr. Jacobs, if you could——

Dr. JACOBS. I am sorry, but I think it is high money. It's——

Mr. GORE [continuing]. We will call on you again.

Dr. JACOBS. $3,800 an hour is pretty good money.

Mr. GORE. We will call on you again in a minute.

Dr. JACOBS. OK.

Mr. GORE. Dr. Salvatierra.

Dr. SALVATIERRA. No, but just for the record, in that the statement has been made, the usual reimbursement that is made for the procedure—and this includes the pretransplant evaluation, the surgery and 2 months followup of the patient, most of this done during a hospitalization—the reimbursement for that procedure is approximately—one can charge whatever, but the reimbursement most people are seeing is in the range of $1,500 or $1,600. Now, that, in most instances, is returned back to the university in that most transplant surgeons are university surgeons.

In addition, as far as what the patient sees—and I know this is the practice at my center and at other centers—a patient does not see any statement whatsoever for professional fees to be reimbursed. Unfortunately—I mean, these patients are in an unfortunate situation after a chronic illness and the last thing we want to do is to exercise in any way some pressure toward reimbursement.

In regards to the living related group, there are some considerations here. Transplantation has been changing, and I think what Dr. Jacobs has been referring to is the fact that in the living related group there is only a small chance that one might come up with the ideal match situation.

Under a procedure that we have ourselves instituted at our institution, it is now possible to work with incompatible family member donors to the point that the expectation from transplantation is greater than 90 percent.

I should also indicate—and there is, I think, inferred, you know, maybe this might be tried, so forth, but I would also like to indicate that our institution, at a time when there was little public awareness of the needs of these patients, under an NIH grant and under tight control of a human experimentation research protocol at the institution did proceed with transplantation from 22 unrelated donors.

The evaluation to finally get those 22 unrelated donors to the point of giving a kidney was much more extensive than what we usually employ with the living related, particularly in regards to the psychologic considerations. Sometimes in trying to be accurate about past medical history, when you are dealing with a family, that past medical history is more easily affirmed.

But to get to those 22 so that they satisfied the criteria that it was, yes, OK to go ahead with the transplant, we screened almost four times as many patients. The final result was that the results of those kidney transplants provided no better outcome than if a cadaver kidney was used.

You are right, Mr. Gore, in terms of living related transplantation. If cyclosporin becomes accessible and with the results that are currently being reported, maybe living related transplantation will certainly not be as frequent a procedure as it is currently today.

Dr. Jacobs. Could I finish my comments that I was making before?

Mr. Gore. Well, we are going to have to—I am going to give you a chance at the conclusion, Dr. Jacobs. We need to—we've got a vote on the floor. We need to move along, and we will give you a full opportunity.

I have a number of other questions, but I am going to hold off and recognize my colleague, Congresswoman Schneider.

Mrs. Schneider. Dr. Salvatierra, I wonder if you could expound upon the reasoning that would exist. Why would anyone donate an organ if there was a market for the sale and purchase of organs?

Dr. Salvatierra. I think the primary reason would be a monetary one.

Mrs. Schneider. And Dr. Jacobs, do you not agree with that?

Dr. Jacobs. Of course. That doesn't mean it's a bad kidney. In fact, a kidney has a better chance—see, you are missing one point. You take a cadaver, a brain dead person, you have a few days in which to get the kidney out before the pneumonia sets in and infection sets in.

The healthy person, between—again, one out of four he has screened. He accepted one out of four healthy unrelated and transplanted them, mostly successfully. You are talking about months between when the person first makes an application, getting their medical records from their family physicians and the clinics they go to. It takes months to go through psychological screening, blood tests, kidney x-rays, et cetera. In those periods of months, if they have some diseases, something will show up. So, you are testing them for blood tests and transmittable diseases, et cetera.

Whereas with a cadaver, someone in a car accident, lying in a hospital, with the emotional state that takes place there, in the cadaver situation, you don't have months. You have hours, a day or two at the most. You don't have time to get all their medical records. The family is emotionally distraught. How do you get a proper medical history from a family under those circumstances?

The risks of the person now getting a cadaver kidney on those theoretical risks is much greater than taking it from a stranger, a healthy unrelated person, who is fully evaluated and rejected if they have transmittable diseases, rejected if they are malnourished, rejected if they are psychologically bad.

Mrs. Schneider. Dr. Jacobs, you are changing the focus of my question, and the focus of my question is to emphasize the fact that if there is a price tag put on organs——

Dr. Jacobs. For those that can afford it, and for those that can't, they have the current system.

Mrs. Schneider. But why would the current system operate at all? I mean, if——

Dr. Jacobs. The current system will operate and will not be interfered with. The current—there are always going to be people out there whose family members will be approached and will want to give up a kidney for free. No one is ever going to pay for a brain dead individual lying on a respirator. There is no question about that.

Second, how are you going to find them? You know, you are talking about the practicalities of logistics. It will not ever happen.

Mrs. **Schneider**. I am talking about who would ever give their kidney up, who would ever make a donation for free if it were possible to sell it?

Dr. **Jacobs**. They can't sell it. You are talking about the brain dead person who can't make the decision, so you are talking about their family members in an emotional, distraught situation. Who is going to buy it? You have to match them to a paid system? It will never work.

The only cadaver system—the only cadaver system that exists now is the one that exists, and there are people waiting who already have been matched and waiting for the brain dead person to arrive. We are not talking about depleting the cadaver pool. In fact, we are talking about augmenting the cadaver pool because people when they are alive can make the decision when they are alive to sell a kidney if they die, and the Government can pay for it. The Government can equitably distribute it, and that will probably solve the entire—why should someone give up a kidney now when they are dead? Most people don't.

Mrs. **Schneider**. Thank you, Dr. Jacobs.

Dr. **Jacobs**. If you sell it, most people will.

Mrs. **Schneider**. We are under the pressure of time.

Dr. Brams, I'd like to hear your response to those comments, please.

Dr. **Brams**. I think in answer to your question, first, there will be ample opportunity for an altruistic market to flourish. We can see that as, for example, transplants say between husband and wife and vice versa, between father and son, between mother and daughter, between brother and brother, sister and sister.

So, those kinds of transactions, those kinds of transplantations I think are unlikely to be very much affected by commerce. Those kinds of organs will probably continue to be transplanted under the altruistic system simply because the motivation and close relationships is largely altruistic; not exclusively, but I think largely.

So, when we talk about the financial incentives for organ transplants, I think basically we are talking about incentives between unrelated donors, where there is virtually no interest on the part of the donee in the health welfare of the donor and the health and welfare of the donee.

So, the financial incentive, I think it is necessary to make connections between unrelated people. It would be nice if altruism did produce an adequate supply of donors, but the problem is it hasn't done so. And I think the deficiency with that view is that it's based on a view of the way man ought to be, not on the basis of the way he is.

Mrs. **Schneider**. I think that we have a system in place right now, the voluntary system, and it does not, to my way of thinking, seem appropriate that we should immediately embrace another system, the buying and selling of organs, without really giving the effort necessary to improve upon the voluntary system.

Now, I can tell you that my constituents in the State of Rhode Island are only aware that, you know, there is such a thing of organ transplants to a limited degree because of the benefit of the television stations and other media exposure.

But can you imagine what would happen if the Governor or other elected officials were to move ahead and have a major public education effort, in cooperation with the medical profession, and to encourage people to voluntarily sign up to donate their organs.

Believe me, before this year I was never aware of it, and I would never have thought of doing it. Not until I had that information.

Dr. **Jacobs**. Have you signed up yet? Have you signed up yet?

Mrs. **Schneider**. Yes, as a matter of fact, I have.

Dr. **Jacobs**. Then you are one of the rare people because the proof will be in the pudding, as I told Waxman at the end. You'll see that if you make it illegal—well, you don't even have to make it illegal now. Dr. Salvatierra's group, whose antitrust business has made it basically forbidden anyway.

So, the point is you will see in a couple of years all your better computers, all your education to the public, and you will see. The proof will be in the pudding. If you can achieve it voluntarily, more power to you, but why should you interfere with another parallel system that is going in the same direction.

Mrs. **Schneider**. I think that certainly the effort is worth it to see if this so-called experiment would work rather than——

Dr. **Jacobs**. Yes, but why interfere with the parallel system?

Mr. **Gore**. Dr. Jacobs, we will continue this after the vote.

Let me say to my colleague that the Centers for Disease Control conducted a pilot program to work with the hospital emergency room personnel, doctors, emergency care nurses and others, and found that that pilot program increased by 300 percent the number of kidneys voluntarily donated.

If we have a similar nationwide effort to increase the awareness in the proper areas and within the public as a whole, then I believe that we can make this current system work.

Dr. **Jacobs**. Then fine. That's great.

Mr. **Gore**. Let's continue this discussion. We have a vote on the floor.

Dr. **Jacobs**. What time shall we come back?

Mr. **Gore**. We will come back in about 10 minutes, Dr. Jacobs.

Dr. **Jacobs**. I will be here.

Mr. **Gore**. It will be a brief recess and then we will continue.

[Recess.]

Mr. **Gore**. The subcommittee will come back to order. Sorry for the delay. We had a quorum and a vote on the floor.

Let me ask a couple more questions before we move to the final panel.

Dr. Brams, you say in your testimony, as you earlier wrote in the American Journal of Law and Medicine, that a decrease in the supply of free organs seems a reasonable price to pay for an overall increase in the availability of organs.

You are assuming in your statement that there would be an overall increase?

Dr. **Brams**. Absolutely.

Mr. GORE. If you were presented with evidence showing the likelihood that there would be an overall decrease—in other words, that the decrease in voluntary donations would be larger than the increase in paid donations—then that would completely reverse your view, would it not?

Dr. BRAMS. Well, if—sure. I mean, if as a result of legislation that permitted buying and selling of organs——

Mr. GORE. Could you use the microphone?

Dr. BRAMS. If it turned out that legislation permitting the buying and selling in organs did in fact cause an overall reduction in the supply of organs, combined between altruistic donation and commercial donations, then, of course, it would not be a good idea if the aggregate supply were less. But I think that is an unlikely scenario.

Mr. GORE. Well, now you say in your article that the current, quote, "The current mixed voluntary commercial blood system provides a precedent." End quote.

What would you think if I told you that the experience with blood sales was that the increase in paid blood donations was, in fact, smaller than the size of the decrease in voluntary blood donations, and that after the buying and selling of human blood first began there was a rather sharp drop in the overall availability of blood? If you seek to use that as a precedent, it would seem to point you in the opposite direction.

Dr. JACOBS. You are mixing apples and oranges.

Mr. GORE. Excuse me, Dr. Jacobs.

Dr. BRAMS. Well, if, in fact, it is true that a system of voluntary donation of blood plus a commercial supply gives you an overall supply which is less than if you relied solely on voluntarism, that would be an argument against a commercial supply.

But I really don't believe that that is the case. Moreover, even if it were the case, it doesn't necessarily follow that a market for kidneys would behave in the same way as a market for blood. I think there are similarities there, but it doesn't necessarily——

Mr. GORE. What is your evidence for supposing that it would behave differently?

Dr. BRAMS. Two pieces of evidence. One piece is simply that everything we know about human behavior in this system suggests that people are simply responsible—are responsive to financial incentives. It's the way the system is and, as far as we know, it's the way people generally behave. They are responsive to financial incentives.

Mr. GORE. No, no. I'm asking for evidence that would lead you to suppose that it would be different in the case of kidneys than in the case of blood. Presumably your axiom that you have just laid out would have led to—would have led you to believe that there would be an overall increase in the availability of blood once the commercialization began.

What evidence do you have to believe that, to lead you to believe that it would be different? You can look at England as an example. They outlaw the buying and selling of human blood. The availability of blood per capita, the rate of donation in England is far higher than in the United States, and many believe that that is one of the principal reasons why. People feel they are suckers donating blood for free—some people do—if they could get money for it. In fact, Dr. Jacobs was quoted a few months ago as saying that anyone who gives an organ for free is a sucker because he ought to be getting——

Dr. JACOBS. That is not quite what I said.

Mr. GORE. It's close. Close, isn't it?

Dr. JACOBS. It's not that close, either, no.

Mr. GORE. Well, I will come back to you, Dr. Jacobs.

Dr. Brams, go ahead.

Dr. BRAMS. Two responses. One is I think with respect to kidney donations the financial incentive to donate a kidney is much, much greater than the financial incentive to donate blood. A person donates blood, I guess it is maybe $15 to $25 a pint. A person donates a kidney, we are talking about several thousands of dollars, maybe tens of thousands of dollars. So, I think the magnitude of the incentive is much greater.

Moreover, for years now there have been scattered accounts in the media of people actually offering kidneys for sale at various prices and there have been a number of accounts of people who have been willing to purchase kidneys at various prices.

And that is my—that is my response. Moreover, what we know about this system is that other things being equal, an increase in the price of anything is likely to induce an additional supply, anything all the way from pretzels to kidneys. It's simply the way the system works.

Mr. GORE. Not if you are getting it for free now.

Dr. BRAMS. No, but the point is we are talking about people who aren't getting it for free because there are not enough people who are willing to donate for free. They simply are not getting it.

Mr. GORE. Dr. Jacobs, first of all, let me give you a chance to comment, and then I have some specific questions.

Dr. JACOBS. Yes, the few specifics I wanted to discuss, some of which Dr. Salvatierra raised and others.

Regarding blood and kidneys, they are totally—you are talking about apples and oranges. You are talking about, you know, giving a pint of blood and coming back in 2 months and giving another pint of blood. You are talking about a repetitive, donative act versus giving up a kidney with all the additional considerations that one has to put into it. It is—you are not talking about the same thing.

Mr. GORE. Well, I would think that would point toward even worse outcomes with kidneys than with blood.

Dr. JACOBS. The outcome couldn't be any worse than it is now. I mean, you have got——

Mr. GORE. Sure it could.

Dr. JACOBS. You've got a voluntary disaster that's been sitting there for years and has not significantly improved.

Mr. GORE. Now wait a minute. Let's keep it in perspective. It has significantly improved year by year——

Dr. JACOBS. What, from 2,000 to 3,000 to 4,000 to 5,000?

Mr. GORE [continuing]. From zero to almost 6,000 per year——

Dr. JACOBS. And if it keeps on improving——

Mr. GORE [continuing]. And there is a steady improvement year by year by year. There are about 10,000 people on the transplant list. About 6,000 of them are getting transplants each year. That's a rather remarkable success rate, given the fact that this new era of transplantation is so young. It is still—we are still not solving the problems, but we are going to build on that record of success and until all those who need transplants are able to get them.

Dr. JACOBS. And if it keeps going the way you are saying it keeps going, and if it keeps rising, more power to it. Then what is all this legislation about?

Mr. GORE. Pardon me?

Dr. JACOBS. If it keeps going the way it is going, then what is all—what's all the need for legislation about? I am talking about the legality part, not the other end.

Mr. GORE. Yes. Well, the reason for the ban on buying and selling in that context—there are many reasons for it, but in that context, many are concerned, and many who've testified here today are concerned that the opening of a marketplace would stop that progress and actually reverse the direction.

Dr. JACOBS. OK. Let's go into that point because that's really a critical point to what your problem is about here.

If you have 5,000 people who are brain dead—now we are talking about brain dead cadavers now, we are not talking about healthy living. We are talking about—see, that is the problem here. You are also talking about apples and oranges. You are mixing and matching the brain dead versus the healthy living.

A brain dead person is going to be in the grave. It's up to their family at this point, the way things are set up—it's up to their family to say, is the organs going—are the organs going to be harvested, as Dr. Salvatierra's groups call it. Are the organs going to be removed for transplantation, or are they going to go into the grave with the brain dead individual?

Mr. GORE. And I am saying that if you offer them money, you're going to make it less likely that we can increase the rate of voluntary donations.

Dr. JACOBS. Oh, well, that's the point. I think that is where you are wrong. Let me just clarify that.

That's the key point here. That really is the key point. So, you have 22,000 lying brain dead last year, according to your figures. Let's assume 22,000. And 2,200 of them, 10 percent, because they have two kidneys, 10 percent voluntarily—they didn't, but their family agreed to have the kidneys given away free to the closest match.

What you are trying to say is that that 2,200, that 10 percent, will be either diminished, where they won't give it up at all, which is your worry, or that 2,200 will move into a financial for sale program. It is still the same 2,200 donating kidneys. It's just a matter of distribution, to the rich or to those that are waiting for it. That's your moralistic concern.

But look at it from the other point of view. What if instead of 2,200 of those 22,000 people end up giving up organs? Instead of 2,200 what if 5,000 give up organs; 2,200 for money and 2,000 give it up free. Let's say 3,000 family members who want money for it and with the Government and the computers that you are trying to set up, let's say they can get paid by the Government for giving up their organs, so that's the monetary incentive. This is the monetary incentive after the fact. How about the monetary incentive before the fact, before they—before people die, so they can decide with their—they can will their body for money, should it come that way. It's just raising the numbers. That's the point, the numbers.

Mr. GORE. Do you understand—do you understand the concern that someone who voluntarily donates might look at voluntary donation differently, if that person had read in the newspaper that he or she could get money for organs——

Dr. JACOBS. Suppose they could——

Mr. GORE. Let me just finish——

Dr. JACOBS. But they are still going to give up——

Mr. GORE. Let me just finish this question.

Dr. JACOBS. But they are still giving up the organ, they are still giving it up.

Mr. GORE. They may or may not be.

Dr. JACOBS. Well, how are they not going to give it up?

Mr. GORE. Well, wait a second.

Dr. JACOBS. They would have given for free. They will certainly give it for money.

Mr. GORE. Well, that's——

Dr. JACOBS. That's the point. Come on. We are in America here now. Let's take Tennessee as part of America here. We are not in Russia, OK? So, the point is, if they would have given it up, they would have given it up for money or they would have given it up for free. That's just the point. They would still give it up. So, if the Government is going to pay them for it, let the Government do it and equitably be distributed. So, if the Government is going to do it, what the heck does the recipient care? What does the recipient, the one on dialysis, care if the Government paid $5,000 or $50,000 for the kidney that they got? What do they care?

Mr. GORE. Didn't you yourself say—you said I misquoted you earlier, but didn't you say something to the effect that somebody's crazy to donate for free because they ought to get money for it instead?

Dr. JACOBS. Not in that context.

Mr. GORE. What did you say? What were your words? You said——

Dr. JACOBS. This is the context, and listen to me.

Mr. GORE. You said essentially that, didn't you?

Dr. JACOBS. But not out of context. You put it in this context. The point is, when the person is brain dead—there are three categories we got to talk about. You are talking about the brain dead people, the healthy related people, and the healthy unrelated people. They're three separate pools and they don't mix and match in this room or anyplace.

They're three separate categories and you can't mix them together. Salvatierra is trying to mix them and match them. They're not. You have the brain dead people, who are brain dead. Their family members have to decide what to do with their organs. Most of them now—all of them now who give it up, which is 10 percent—you are not listening.

Mr. GORE. Yes, I am.

Dr. JACOBS. OK. Well, I am here—if you want to hear it, I will say it. I don't read out of—I don't read prepared statements here.

Ten percent of the people—I am trying to give you information—10 percent of the people now who are in that situation, their family members give up a kidney, give up their organs for free. They still would give it up for free. Now maybe—maybe if you say you are worried about all those 2,200 people and say well, we want to sell the organ, so let the Government buy it and give it away to the best match. So what? They still are going to save $2 billion a year. It's a nickel and dime thing, $5,000 when they are going to save $25,000 to $30,000 a year, a year per dialysis patient?

Mr. GORE. Well, nobody——

Dr. JACOBS. The point is, we are hoping—let me finish what we—let me finish a minute. Give me that little courtesy.

What we are hoping is—what we are hoping is with a monetary incentive the brain dead family members, the family members will say look, I wouldn't have given—I wouldn't have wanted Joe Doe to give up—my brother to give up the kidney and let's bury him with the organ, but for $10,000 maybe, well, we could use the money and his family could have it and his burial expenses.

Whatever the reasons, the point is so instead of 2,200 people having organs given up, maybe you will end up with 10,000 and it will solve the whole problem in one fell swoop of the ones that are now in the system.

The other half of the monetary incentive is when they are healthy and alive, let them decide what they want to will their body for. And if the Government equitably distributes it to the recipients so there is no rich and poor criteria there, what's the problem with that? And if that doesn't meet the—if that doesn't fit the bill, if that is still not enough, then you have the voluntary, healthy paid people who are nowhere in the other system at all, so it's just supplementing what's now not enough. That's all we are talking about.

Mr. GORE. Why do you think that the buying and selling of blood resulted in a lower rate of donation overall?

Dr. JACOBS. I don't think it has. You are talking about—there's more blood available now than—there is a surplus of blood available now. Not at Christmas peak time, not with the Christmas accident season. There is plenty of blood available now. And the plasma, by the way, is still for sale.

Mr. GORE. But there was a sharp decline in the overall rate of blood donation when commercial sales started.

Dr. JACOBS. Because people probably wanted to get money for it.

Mr. GORE. Yes, that's the point.

Dr. JACOBS. But still the same blood is available.

Mr. GORE. No, it wasn't. There was less blood available.

Dr. JACOBS. That was back years ago and we are talking about——

Mr. GORE. It's still the case. It's still the case. We still have——

Dr. JACOBS. If this is the case——

Mr. GORE. Wait a minute. Wait a minute.

Dr. JACOBS [continuing]. Then go for sale again.

Mr. GORE. Wait a minute, Dr. Jacobs. Why do you think we have a lower overall rate of donation here than in England, where buying and selling blood is outlawed? Why do you think that is the case?

Dr. Jacobs. I can't give you that answer, but what I can tell you is very simply if there is not enough blood available now, if there isn't enough blood available now, the best way to make it available is to pay for it. Screen the donors and pay for it.

If that's your problem with not enough blood available—we are here about kidneys—if that's the problem, pay for it. I can assure you people will be walking in, supermarket fulls of people will be coming in to sell their blood, a renewable, replenishable—every couple of months they can give another pint of blood.

Mr. Gore. That is just not what happened. That's just not what——

Dr. Jacobs. You give enough money to someone—it's just a marketplace. You give people enough money, they will sell their blood.

Mr. Gore. It's not just a marketplace because people——

Dr. Jacobs. I know, are different. They aren't things. I know they are not things. They are not car bumbers, according to Waxman. He changed your line a little bit. That's very nice. The point is—and it's good his voters are in Los Angeles——

Mr. Gore. But, you know, it is not just a line, either. It's a principle.

Dr. Jacobs. It's your moralistic principal. We are here—look, the point is that if you have 2,200 people that gave organs last year who, excuse me, who family members allowed their dead relatives to give up organs last year for free, if the Government gets involved and gives them $5,000 or $10,000 or $15,000 or $25,000, whatever the amount of money is to raise the donation, some will still give it for free. So what? If they all sell it, the Government is going to buy it and equitably distribute it. What's the difference?

Mr. Gore. Let me move to another——

Dr. Jacobs. I know you don't like that.

Mr. Gore. Pardon me?

Dr. Jacobs. I know you don't like that, but that's where it's at. And so if the Government can buy it and—if the Government can buy it and distribute it—listen, we are not on "Nightline" here. If the Government can buy it and distribute it, if they can buy it and distribute it from the brain dead and they can give the monetary incentive; the healthy, should they end up in that unfortunate situation, in advance should make the decision, there is no difference there. They still get kidneys. And if that's not enough——

Mr. Gore. Well, but you keep repeating that same assumption over and over and over again. You still have the voluntary donations, but you may not still have the voluntary donations. That's the assumption——

Dr. Jacobs. Where are going to go?

Mr. Gore. That is one of the assumptions I am challenging.

Dr. Jacobs. Where are they going to go? Where are they going to go?

Mr. Gore. They are going to——

Dr. Jacobs. They are going to say I don't want it for money and I would have done it for free, but now that you are paying for it I won't do it. That's what you are saying?

Mr. Gore. That happens——

Dr. Jacobs. That is exactly what you are saying.

Mr. Gore. That happened with blood. It happened with blood.

Dr. **Jacobs**. It will never happen with kidneys, and if you give enough——

Mr. **Gore**. Just here today, just here today Mrs. Engebretsen testified that a parent called her and said, "I tried to find you to sell this organ and now it's too late because it can't be done." It's not that hard for me to understand that if people—if you are telling people that they are suckers to——

Dr. **Jacobs**. I am not calling them suckers.

Mr. **Gore** [continuing]. Donate for free, it's not hard for me to understand that they—it's a hard enough decision, after all. It's a hard enough decision, and for them to be confronted with this haggling over price, a marketplace, all the rest——

Dr. **Jacobs**. There is no haggling.

Mr. **Gore** [continuing]. It is not hard for me to see how they would say, "I just don't want to get involved in that. It's a time of stress. Just forget the whole thing."

Dr. **Jacobs**. There is no haggling. The Government says there is $20,000 for the organs, or $30,000. Whatever the fixed price the Government sets will be sufficient to increase the number. That's all.

Mr. **Gore**. Well, your proposal changes from week to week.

Dr. **Jacobs**. No.

Mr. **Gore**. It evolves from week to week, because earlier you were saying that the price would be set by bargaining between you, as broker, and the potential donor.

Dr. **Jacobs**. We are talking about the healthy living now, and I was just talking about the brain dead. Two different market spheres.

Mr. **Gore**. OK. Well, now on the healthy living——

Dr. **Jacobs**. That is a different situation now.

Mr. **Gore**. What you are talking about is haggling about the——

Dr. **Jacobs**. No haggle. No haggle.

Mr. **Gore**. Bargaining, then?

Dr. **Jacobs**. No bargaining. The healthy living——

Mr. **Gore**. How are you going to set the price?

Dr. **Jacobs**. The healthy living person who is going to sell—if you are going to sell your kidney, if you are going to, you will say I want *x* thousands of dollars for the kidney. That's your price. That is the price. That's the only price. Your blood test goes into a computer, your code number for your name, your price next to your code number, and your blood types go to the doctor and the recipient.

Mr. **Gore**. So, the seller just sets whatever price he or she wants?

Dr. **Jacobs**. That is correct. That's what I said before. That's what I said before Waxman. That's exactly what I said on Nightline. You were sitting next to me there. That's exactly it. There is no haggling, there is no argument.

Mr. **Gore**. You said at one point that you got the idea for this while watching television reports of mass deaths in Bangladesh.

Dr. **Jacobs**. No, no. Let me tell you—I said on Nightline, so I will say it again to you. You were sitting next to me.

Mr. **Gore**. No, you were quoted in a newspaper as saying that——

Dr. **Jacobs**. That's not quoted right.

Mr. GORE [continuing]. In the Post as saying—and it's also——

Dr. JACOBS. That's not what I said.

Mr. GORE. You are also on film saying the same thing.

Dr. JACOBS. What I said was I watched Nightline when Denton Cooley was on, and Jarvik was on about the Barney Clark episode back about 6 or 8 months ago.

Mr. GORE. You said that later. Again, your statement of where the idea came from changes from week to week, also.

Dr. JACOBS. Yeah, that's where the idea came from.

Mr. GORE. Well, you are quoted——

Dr. JACOBS. The next morning—excuse me. The next morning, on the front page of the *Washington Post*, there was the slaughter in Bangladesh. So, from what I saw the night before about Denton Cooley, about the natural organs are better than the artificial organs, which, of course, I knew anyway, stimulated me when I saw the *Washington Post* article the next morning about all the dead bodies laying around and I said it's a pity that once they're dead you can't use the organs for all the people—and about—I'm an inventor and as days passed, it suddenly clicked. I said why can't we get into a marketplace, and that's what happened and that's what I said on Nightline and that's what I said to the Post and that's how it—that's how the idea came into my head. I wrote to 7,500 hospitals, a brochure——

Mr. GORE. Some of those poor people in Bangladesh might be willing to get some money by letting you take their kidneys out.

Dr. JACOBS. Same thing with anybody in this country, rich or poor. That's on the voluntary system, now. It has nothing to do with the brain dead system. It's two different spheres.

Mr. GORE. Do you see anything wrong with—let's say you get a 747——

Dr. JACOBS. And fill it full of Bangladesh people.

Mr. GORE [continuing]. And fly it over to Bangladesh and you go out to the poor areas and——

Dr. JACOBS. And give them food or money.

Mr. GORE [continuing]. You offer them——

Dr. JACOBS. Food or money.

Mr. GORE [continuing]. Thousands of dollars, something that's three or four times the——

Dr. JACOBS. Annual wage.

Mr. GORE [continuing]. Annual average income——

Dr. JACOBS. That's correct.

Mr. GORE [continuing]. And you fill up the 747——

Dr. JACOBS. First having screened them physically and psycho——

Mr. GORE [continuing]. With low income——

Dr. JACOBS. Well, you have to screen them first.

Mr. GORE. Well, wait.

Dr. JACOBS. OK.

Mr. GORE. You fill up the 747 with low income, poor citizens of Bangladesh——

Dr. JACOBS. Just like Salvatierra did for 22 Americans.

Mr. GORE [continuing]. Who need money desperately. You screen them for diseases and blood types, and then you have the 747 take off and fly to the United States and then you——

Dr. JACOBS. Remove the kidneys.

Mr. GORE [continuing]. Carve them up and take a kidney out of——

Dr. JACOBS. We call it a nephrectomy.

Mr. GORE [continuing]. Each one of them and give them the money. Do you see anything wrong with that?

Dr. JACOBS. Yes; if you don't do the following, I see things wrong with it. You have to do more than that. You've got to screen them psychologically up front. You have to be sure that there are no infectious diseases.

Mr. GORE. Are you going to screen them? Are you going to have an interpreter and a psychiatrist?

Dr. JACOBS. Doctors and psychiatrists, psychologists in their own countries first, fully—they have hospitals there, too.

Mr. GORE. How many psychiatrists do you think they have in Bangladesh?

Dr. JACOBS. Well, the point is we will have to hire them, won't we? They at least have one. We will hire him. The point is no one is going to be touched until the same criteria Salvatierra used for the 22 Americans he carved up unrelated as the strangers from Bangladesh, if it comes to that. It's the same criteria.

Mr. GORE. Let me ask you this. Let's say you've got one person in Bangladesh who is having trouble feeding his family——

Dr. JACOBS. Correct.

Mr. GORE [continuing]. And you're offering him two or three times the annual wage in Bangladesh and he says, "OK, take my kidney."

Has that person given you informed consent?

Dr. JACOBS. Not at that point he hasn't. A lot more has to be done before that point.

Mr. GORE. What else?

Dr. JACOBS. Well, first off you have to—No. 1, you have to be sure—you have—the doctor has to be sure that they are healthy, so you do all the appropriate blood testing, chest X-rays, rule out tubeculosis—you know, do everything that Salvatierra did to the Americans and more, because there are other types of diseases, so you gear it to the population. So, you have to go overboard even more to protect that person, number one.

No. 2, you have to have them psychologically screened so that he knows, the person knows, No. 1, what a kidney is, what happens if you take out one, the risks of surgery, the risk of an operation.

Mr. GORE. And he says, "I don't care about all that."

Dr. JACOBS. Then he is rejected if he doesn't care about that. He's rejected. It's very simple. He's rejected. It's the same as an American. Salvatierra rejected 60 for the 22 he took. It's the same—it's the same criteria, the exact same criteria because there is more. When they come to America, it is done all over again.

Mr. GORE. So you are going to——

Dr. JACOBS. You asked me a question. Let me answer it.

When they come to America it is done all over again, the psychological screening, the physical examinations, the blood tests, the evaluations, and then they have had months between when they are first contacted to when they come here, months intervening, so they again have thought about it, and then they are properly selected, and then after all these criteria are met, the operating surgeon, the American surgeon at the American hospital again has to get informed consent, go through all the procedures that Salvatierra has gone through.

Mr. GORE. Now, you said earlier—and I asked you about this before—but you said that some of them might be willing to come and have their kidneys removed for very little money, because they would get a chance to see America.

Dr. JACOBS. No; you said that on Nightline.

Mr. GORE. No; you said that.

Dr. JACOBS. I agree with you.

Mr. GORE. You said that. I was quoting you.

Dr. JACOBS. If that's so, fine.

Mr. GORE. They could come and see the Statue of Liberty and a kidney would be a small price to pay.

Dr. JACOBS. Their motive is not important.

Mr. GORE. What if they wanted to sell you——

Dr. JACOBS. What if they wanted to do it for free?

Mr. GORE. What if they wanted to sell you a cornea?

Dr. JACOBS. We are not talking about mutilation.

Mr. GORE. What is the difference? Tell me the difference.

Dr. JACOBS. The difference is that if you take out one eye, you are mutilating the person because they are blind in one eye, No. 1; No. 2, they lose their peripheral vision to the left side and they lost their stereotopic vision for—it's important in operating harvesters or operating—dropping seeds in holes.

Mr. GORE. Well, there are detriments—you gloss over them very quickly but there are health detriments associated with having one kidney removed.

Dr. JACOBS. There are and they have to be followed when they get back to Bangladesh, and that has to be set up, too. You can't just take——

Mr. GORE. Well, is a psychiatrist going to do that?

Dr. JACOBS. The physician clinic that sent——

Mr. GORE. So, is the one psychiatrist going to follow up on all these patients?

Dr. JACOBS. No; they have physicians there, and the physicians will be checking up. By the way, this is an important thing, where Salvatierra said that the healthy mother that gives up the kidney is followed very, very carefully. Followed for what? If the other kidney fails, what has she got? She's got no kidneys.

Mr. GORE. So you agree that there are health detriments associated with the removal of a kidney?

Dr. JACOBS. There is a very small health detriment, the same detriment to Salvatierra's moms and pops and brothers and sisters as to the Bangladesh. It is the same detriment.

Mr. GORE. Now wait a minute. Do you find it offensive to think about someone selling his or her eyeball for money?

Dr. JACOBS Absolutely. It's not the money. You are mixing up motivations and physical medicine, OK. Motivation is not—let's forget about the motivation. To give it up for money, it's not important. They are blind in one eye. You've blinded somebody in one eye. You've mutilated them. There's a difference.

Mr. **Gore**. Is the difference that in one case it's on the outside where you can see it, and in the other case it's on the inside where you can't see it?

Dr. **Jacobs**. No; because, as Salvatierra says, you can live a healthy, normal life. He just said it this morning. You can live a healthy, normal life with——

Mr. **Gore**. You can live a healthy, normal life with one eye.

Dr. **Jacobs**. No; not a normal life. It's not a normal life. You've lost——

Mr. **Gore**. Well, you can't live a normal life with one kidney.

Dr. **Jacobs**. That's the point. You can live a normal life with——

Mr. **Gore**. You can live a near normal life.

Dr. **Jacobs**. [continuing]. A normal life, a perfectly normal life with one kidney, whereas you can't immediately and ever live a normal life with one eye. That's why it is mutiliation. That's why Salvatierra is still operating on healthy related mothers and sisters. That's the difference. It's a big difference.

Mr. **Gore**. Now, you are going to have an intellectual discussion with some barely literate——

Dr. **Jacobs**. I'm not. People speaking their own language will have an absolutely clarified, longstanding, ongoing discussion from the lowest level to the highest level before anybody is—we are just talking it academically right now because there is no proposition here. We are talking academically.

The same informed-consent criteria has to be met because they are operated upon in this country. The problem that you are setting up is if you make it illegal in this country, because remember, the operation is still done here, if you make it illegal in this country, it will happen like abortions happened 30 or 40 years ago. There is no control then.

Mr. **Gore**. OK. We have time constraints, unfortunately. I would like to go on, but I think that——

Dr. **Jacobs**. I ran out of tape.

Mr. **Gore**. Well, that's just as well because we are going to move on to the next panel.

Do you have a comment to make, Dr. Salvatierra?

Dr. **Salvatierra**. If I could, one other comment. It primarily goes back to my testimony, but I think it is something that is very important to underscore. Why place someone at risk if there are viable, nonrisk alternatives. In other words, why remove kidneys from individuals when we are just currently utilizing a small fraction of what is available?

I believe that this argument and what we have heard today are very compelling arguments to strongly support the legislation that you and others have introduced.

Mr. **Gore**. I appreciate that very much.

Dr. Brams, did you want to make a comment?

Dr. **Brams**. Yes. I think one of the things we have to consider in addressing an issue like this is not only what may be desirable, depending upon your viewpoint, but also what is possible.

Now, I have made a case—and you can make a legitimate case, I think—for allowing commercial markets in organs, at least certain types of organs. But we are probably not ready for anything like that. And so there are several things that can be done. I mean one, if your legislation works and it does in fact solve the problem by providing an adequate supply and distribution of kidneys, fine. No problem with that at all. Try it and see if it works.

We can debate things from here to hell freezes over, but the fact of the matter is sometimes you cannot know whether something will work until you try it and see if it works. I think your legislation might be of that type. My guess is it probably won't solve the problem, but it might mitigate it somewhat.

The next level would be if you wanted to continue to solve the problem or to reduce it still further, you could have a commercial market for organs but you could limit it to deceased donors, providing an incentive for people to leave their kidneys, their corneas or whatever for transplant purposes upon their death, not during their lifetime.

If that works, fine. You made another dent in the problem and it might solve it. If it doesn't work, then at that point you might consider commercial markets for live donors, between live donors and live donees.

So, it's the notion here that nature makes no jumps. It's not only a matter of what is academically desirable. It's also a matter of what's possible. I think your legislation is probably possible. I see absolutely no harm in trying it, and then we will see, because we are not ready for the other yet, in my opinion.

Mr. GORE. Let me thank all three of you very much. We have another vote on the floor. What we are going to do is, we are going to combine panels 3 and 4 and ask all five of our next witnesses to come up to the witness table during the break. It will only be—there's only one vote this time, so it will be about 6 or 7 minutes.

Let me say to the members of this panel that I think we are all in agreement on some things. We want to increase the number of transplants. We want to realize the potential for saving lives and improving the quality of life. We have some very sharp differences on how the best way to go about that is, but I appreciate the debate that we have had. I appreciate your appearance here today. We will continue our work to try to solve the problems surrounding transplantation.

Dr. JACOBS. Could you also solve the parking problem?

Mr. GORE. We have been working on that one.

Thank you very much. We will have a 6 or 7 minute recess and then have our final panel.

[Recess.]

Mr. GORE. The subcommittee will come back to order.

I appreciate the patience of members on this final panel. The hearing has been a little bit longer than I thought it would be, but that's partly because it—because there is so much interest in this.

Let me welcome all of you to this panel: Prof. George Annas, Utley professor of health law at Boston University School of Public Health in Boston; Dr. Barry Brenner, Harvard University Medical School, Brigham and Womens Hospital in Boston; Dr. Robert Veatch at the Center for Bioethics, the Kennedy Institute of Ethics, Georgetown University in Washington; Mr. Arthur Caplan, associate for the humanities at the Hastings Center, Hastings-on-Hudson, N.Y.; and Dr. Samuel Gorovitz, chairman of the Department of Philosophy at the University of Maryland in College Park, Md.

I appreciate all of you coming and participating in this hearing today. We have combined these two panels so that it is now an examination of the legal, medical, and ethical issues. We will preserve the order in which we had intended to proceed, and that means Professor Annas, that you go first. We welcome you. Without objection your statement and the other statements will be put into the record in full. If you care to summarize any portion of it, feel free to do so.

STATEMENTS OF GEORGE J. ANNAS, J.D., M.P.H., UTLEY PROFESSOR OF HEALTH LAW, BOSTON UNIVERSITY SCHOOLS OF MEDICINE AND PUBLIC HEALTH, BOSTON, MASS.; BARRY BRENNER, HARVARD UNIVERSITY MEDICAL SCHOOL, BRIGHAM AND WOMENS HOSPITAL, BOSTON, MASS.; ROBERT VEATCH, PH. D., PROFESSOR OF MEDICAL ETHICS, KENNEDY INSTITUTE OF ETHICS, GEORGETOWN UNIVERSITY, WASHINGTON, D.C.; ARTHUR L. CAPLAN, ASSOCIATE FOR THE HUMANITIES, THE HASTINGS CENTER, HASTINGS-ON-HUDSON, N.Y.; AND SAMUEL GOROVITZ, DEPARTMENT OF PHILOSOPHY, UNIVERSITY OF MARYLAND, COLLEGE PARK, MD.

Dr. ANNAS. Thank you, Mr. Chairman. I will take you up on your invitation to try to just hit the high spots of my testimony. I appreciate the opportunity to testify in front of the subcommittee on this issue.

To begin, I think that the best arguments probably in favor of prohibiting the sale of organs in this country have been made by Dr. Jacobs. However, I have the uneasy feeling that the case can be presented better. And rather than try to make a partisan plea for one side or the other, I think that, as the only lawyer on the panel today, it's my job to take a couple steps back and just summarize what the law is and what I consider the relevant and appropriate role of Federal legislation in this area.

So, what I plan to do is spend—is focus my remarks first on the issue of a live donor or live vendor selling their organs, speak very briefly on the issue of the next of kin selling the organs of a brain dead corpse, and then make some concluding remarks about the role of the Federal—of Federal legislation.

First, in the area of the living donor—and a lot of this discussion will seem, I am afraid, a little bizarre and sometimes even ghoulish, but that's the nature of the subject matter—the present law is not terribly helpful.

In general, I think it's obvious to anyone that the sale of a vital organ, a heart or a liver, would constitute suicide on the part of the vendor and homicide on the part of the surgeon who removed the organ. So that when we talk about living sellers, we are really limited to nonvital organs, such as kidneys, one kidney, obviously, in someone who has two.

Second, the issue in kidneys really revolves around two more or less ancient doctrines in the law, the doctrine of mayhem and the doctrine of assault and battery.

Historically, mayhem has been a crime which resulted in making an individual less able in fighting either to defend himself or to annoy his adversary, and it did not result in simply disfiguring someone. The theory was that the king had a right to everyone's arms, had a right to use anyone in battle, and that you were essentially derelict in your duty by becoming disfigured.

Modern writers believe that mayhem would not be found in an operation to remove a kidney if there was significant psychological benefit, such as, again, a donation to a close family relative. On the other hand, there is some public policy that says that we should not remove individuals from their productive labor force, and if it turned out that the risk to a kidney donor was significant, mayhem may indeed be an issue. Certainly in the area of donating an eye, I would argue that mayhem and maiming is still very significant.

The second issue is assault and battery and the question is whether or not it's an assault for a surgeon to take out someone's healthy kidney. Unlike mayhem, consent is a defense to assault and battery, and so the real issue there is whether or not the consent is voluntary, and I will get to that later on in my testimony.

But in general, I think that the reluctance of transplant physicians to use nonrelated donors, as Dr. Salvatierra testified to, is based both on some type of emotional response to this but also on the fact that there is some clear potential criminal liability for that type of procedure.

Other areas of the law that are more certain are the constitutional law, which I believe—and I will just state—does not prohibit—would not stand in the way of the Federal Government forbidding individuals from selling their organs. I don't think there is that right to privacy or constitutional right to sell your body parts.

And other problems that would have to be cleared up before a market in organs could be—could flourish would be the question of whether or not an organ is a product, so subject to warranties, guarantees, and product liability law, or whether it is a service, like blood, and therefore not subject to those types of laws.

In general, the issue is the current state of the law is unclear, and if you either want it to outlaw or legalize organ sales, one has to look at the public policy arguments for and against this.

The arguments in favor of sale are two: One, that it would increase supply and, second, that individuals have a right to autonomy, to do with their bodies as they see fit. The supply issue I think you've correctly identified as very problematic. I don't think we know whether it would increase supply or not, but even if it did, obviously we can't justify doing anything just to increase supply. We can't take organs from the mentally retarded or randomly draft people to give organs, et cetera.

The more important and compelling argument is autonomy, what limits can we place on an individual's right to do with his body as he sees fit. The answer is, of course, we place a lot of limits already. The mayhem statutes, as I mentioned before, are, one, we outlaw prostitution, we outlaw third trimester abortions, we have laws relating to occupational health and safety, et cetera.

Even in cases where we permit people to engage in very dangerous activities, like boxing, for example, we make people be licensed to become boxers. We make football players wear helmets, and we are about to make all our citizens use passive restraints in their automobiles.

All of these actions can be viewed, obviously, as paternalistic and invading an individual's autonomy, but I think the public policy rationale is probably best stated in an old New York case from the 1920's, which involved a 51-year-old prize fighter who had fought 300 bouts, and the boxing commission refused to let him fight another bout because they thought it would be dangerous to his health. He thought the statute was unconstitutional and said that the only reason they were forbidding him from taking this risk was his own, purely personal health care.

The New York courts upheld the statute, saying that the societal basis for that statute was to prevent certain brutal and degrading features of boxing and to promote contests that were conducted within the legitimate limits of the sport.

I would argue that a statute outlawing sales could likewise be constitutional and consistent with public policy to prevent the potential brutalizing and degrading features of organ sales and to protect legitimate organ donations.

Now, it's been argued here many times that, well, many of the same arguments that apply to selling your organs apply to giving your organs, and the answer to that, I guess, while we may not outlaw donations is that we believe donors are heroes and obtain a priceless psychological reward for donating; and second, we limit their donations to close family members, and, in general, we respect the rights of families to try to protect each other.

So, that the arguments in favor of sale I would have to say are not terribly compelling. The arguments against sale, obviously there are many arguments. Many of them are philosophical and ethical. I will leave that to my colleagues on the panel.

One legal argument—and I think it's probably the only legal argument—is that voluntary consent is impossible in a situation borne of desperation. Prof. Bernard Dickens, a law professor from Toronto, has made this argument in favor of the many Canadian provinces which actually already ban the sale of organs. He has said that scientific research and medical education should no longer be pursued at the physical cost of the economically and socially deprived, nor should it exploit the needs of the vulnerable.

He goes on to say, "Of course * * * concede that we do permit the poor to enroll in the armed forces in disproportionate numbers and permit them to engage in dangerous and uncomfortable occupations for money," but he distinguished those two categories by saying, number one, that benefits accrue to society as a whole and, number two, that the choices, while difficult, are not coerced, that there are alternatives.

Finally, I think in looking at this area of voluntariness and coercion, the best analogy—at least the best one I have been able to come up with—is human experimentation. We know that we forbid experimenters to give experimental subjects so much money that it would induce them and coerce them to take part in the experiment, and some experiments we forbid outright.

The question—I guess another way to ask the question, is there an experiment that we would devise which we would say it would be OK to do if the subjects volunteer, but it would be improper, illegal, if you will, to do if the subjects were paid let's say $10,000.

The closest experiment I can think of is let's say you wanted to test a new method of preserving a kidney and you needed 100 kidneys from living donors for whatever reason to do this study. Would we approve a study wherein the kidneys were donated voluntarily by 100 subjects, who had volunteered, again, to take part in this experiment, but not approve the study if those subjects were paid $10,000 each for their kidneys.

I don't know the answer to that question, but my guess is that we would find a $10,000 payment coercive inducement and that almost any IRB in this country would not approve the payment. They may not approve the first thing, either, but if they would approve the study without the payment and not approve it with it, we have basically a perfect analogy.

Again, the answer might be well, we let people donate their kidneys to their relatives and that's coercive as well. Indeed it is, but I distinguish that by saying society did not create the—did not create or sanction the coerciveness of that setting and denying a relative the right to rescue a close next of kin just provides an additional burden to the already tragic situation. So, in general I think that the arguments in favor of sale are not very strong when compared to the arguments against it.

In terms of the deceased, let me be even more brief with that. Obviously there were many legal problems with donating organs—with relatives donating organs from dead bodies. That's why we passed—our 50 States passed the Uniform Anatomical Gift Act, which is, as has been noted, silent on the issue of sales.

Only Delaware of the 50 States has dealt explicitly with the issue of selling a relative or a person selling their organ through the gift document mechanism and has forbidden it. A few States, like Massachusetts, have statutes that outlaw the trafficking in dead bodies, and they would also forbid individuals from selling organs. In general, however, the answer is the State law is very confused and probably no one in their right mind would try to sell the organs of a next of kin under the current state of the law, so that you would need a new statute to encourage sales if you wanted to.

In terms of arguments for and against, the only argument for is, again, supply; and the main argument against is probably one that relates basically to motivation of the next of kin and the role we want the next of kin to play in making treatment decisions for their loved ones.

In general, I think that the notion that the next of kin could profit financially from the death of their loved one could lead to all kinds of mixed messages. We are in a stage now where most courts and commentators believe the family should have a more active role in making decisions concerning the treatment of incompetent patients, for example, and the family should play a good role in looking out for their best interests. This would just complicate that issue by giving them a potential financial incentive to see their next of kin dead so that they could profit financially from it. It brings up all the images of coma and becomes very ghoulish.

In general, while I am a little more balanced on the issue of living donors because of the autonomy issue, I see no reason to favor the next of kin selling their organs. Certainly from the testimony we have heard today, that can lead to abuses.

Finally, and very briefly, on what role the Federal Government should take, I would note—and I think it is worth noting—that the law governing medical treatment, consent to treatment, definition of death, organ donation, autopsy, burial and disposition of dead bodies is and always has been exlusively State law, and so unless there is an extremely compelling justification it would seem to me unreasonable and unnecessary for the Federal Government to legislate in this area.

The current National Organ Transplant Act, if I read it right, outlaws the sale of organs on the basis of the commerce clause. While I think that is a possible way to go, it does a couple of things. No. 1, it only applies to organs that actually move across State lines or something that moves across State lines can affect the transplant——

Mr. GORE. Or affects the traffic——

Dr. ANNAS [continuing]. Or affects interstate commerce, correct. I mean, you could stretch the commerce clause to do that. My main concern with that, however, is that it seems to concede one of the major arguments against sale, is that organs can properly be viewed as commercial commodities and that that's the way that you want to regulate them.

I would argue, although not terribly vehemently, that a more reasonable way for the Federal Government to go, if the Federal Government wanted to get involved in this at all, is through the financing mechanisms, since currently the—medicare pays for all organs that are procured.

A simpler and cleaner method would be simply to not permit any reimbursement for the purchase of an organ or for any transplant operations involved or aftercare involved with the use of a purchased organ, that that would be a clean way to keep the State and Federal jurisdictions separate, but also to have the Federal Government make a statement on what they view as a proper role of sale.

Thank you.

[The prepared statement of Dr. Annas follows:]

DRAFT

TESTIMONY
presented before the

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
of the
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

on

Legal Aspects of Organ Sales

on

November 9, 1983

by

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LEGAL ASPECTS OF ORGAN SALES

Mr. Chairman and members of the Subcommittee, thank you for inviting me to address the legal aspects of organ sales. You have identified an issue which is at the core of organ transplantation and yet has received inadequate attention. I hope my remarks will be useful in your formulation of policy on this issue.

There are five basic sales scenarios that have been envisioned and discussed in the literature,[1] but only two could add significantly to the supply of transplantable organs: (1) the transfer of an organ from a living seller; and (2) the transfer of an organ from a "brain dead" corpse upon its sale by the next-of-kin.

I. SALE OF ORGAN BY LIVING DONOR FOR IMMEDIATE TRASFER

(A) Present Law

Under present law, transfers of vital organs, such as the heart and liver, would constitute suicide on the part of the vendor and homicide on the part of the transplanting surgeon. Accordingly organ sales by living vendors (sometimes referred to as "donors" because of the source of the organ rather than the motivation for transfer) must be limited to nonvital organs, such as one kidney in an individual who has two healthy kidneys. Society currently at least tolerates the sale of blood and sperm, but these can be distinguished from organs like kidneys on the basis that they are renewable and their transfer can be accomplished with no or almost no medical risk to the seller.

I know of no cases in which a kidney has actually been purchased from a living seller in this country, although no state or federal laws appear to explicitly prohibit such a transaction. The question of whether such a sale and transfer is "legal" or not rests upon the interpretation of the state's criminal law related to "mayhem," and the criminal and civil law of "assault and battery."

Historically, "mayhem" came from the feudal system and involved rendering an individual less able "in fighting, either to defend himself, or to annoy his adversary." Such an act was a crime because the king had the right to the fighting services of all his subjects. Consistently, cutting off an ear or nose, or simply disfiguring an individual without weakening him, did not constiute mayhem. Modern writers do not believe that courts should find mayhem involved in an operation in which the donor receives a significant psychological benefit (e.g. by donating an organ to a close family member or friend).[3] But a court could find an analogous public policy in preventing the withdrawal of an individual from the productive labor force.[4] Where the only benefit is financial, the question is a more difficult one and may involve a precise calculation of the harm done to the vendor versus the benefit received and the social value of the activity. In the case of a living eye vendor, for example, it seems likely that the sale of an eye should be considered a classic "maim" and subject the physician who removes it from a living seller to criminal prosecution. Consent, of course, is not a defense to mayhem. Further, if the consent of the seller is not valid (because it is not voluntary or informed) the physician removing the kidney could be sued both civilly and criminally for "assault and battery,"and civilly for negligence. The possibilities of these suits, added to the general reluctance of the transplant physicians to use nonrelated donors in any event, make it unlikely that many physicians would be involved in transplantation using vendor kidneys in the absence of statutory clarification.

There does not seem to be any constitutional right to sell your nonvital organs implicit in, for example, the "right to privacy." Although it seems likely that a court would find a constitutional right for a parent (or perhaps any close relative) to donate a nonvital organ in an effort to save the life of the parent's child. Finally, it is unclear whether organ sales would be treated as the sale of a product (and so subject to warranties) or a service; statutory classification would be needed before any large scale program of sales is likely.[12]

The current state of the law regarding sales by a live vendor is uncertain, and state legislation either to permit (with or without regulation) or outlaw the sale of nonvital organs would be constitutional. The question is which action is most dersirable.

(B) Arguments in Favor of Sale

There are two major policy arguments in favor of permitting living individuals to sell their nonvital organs: (1) it will increase the supply; and (2) individuals have a right to dispose of their bodies as they see fit.

An increase in supply, however, is not in itself sufficient justification, since supply could also be increased by "drafting" individuals at random to serve as organ donors, or by using the residents of our mental institutions and homes for the retarded as donors. Moreover, if the only issue is supply, increased efforts to make the present procurement mechanisms more efficient should be exhausted before embarking on a radically new and controversial course.

The second argument is more compelling, but the fact is that we limit an individual's liberty to do what he or she wants with their bodies in many different ways. Mayhem, previously discussed., is one. Others include prostiution, limits on third trimester abortions, Occupational Health and Safety Laws, etc. Even in cases where we permit individuals to risk their lives and health, we often limit the degree of danger. For example, boxers cannot fight unless they are approved by a State Boxing Commission; football players cannot play without helmets; and eventually none of us will be able to drive in cars not equipped with passive restraints. All of these actions can be viewed as 'paternalism' by the government. The issue is not whether the state can act paternalistically (it obviously can) but whether it can justify its action to the satisfaction of its citizens (or, if a fundamental constiutional right is at issue, whether it can demonstrate a "compelling state interest" in interferring with its exercise).

In upholding a statute under which a boxing commission prohibited a 51 year old prize fighter who had fought more than 300 bouts from risking injury, the court found that the risk was not "purely personal" but also of interest to the state; (1) to prevent certain "brutal and degrading" features of boxing; and (2) to promote contests conducted within "the legitimate limits of the sport."[5] A statute outlawing sales could likewise prevent the potential "degrading" features of organ sales and protect legitimate organ donations.

There may be at least two reasons why we might outlaw sales and yet permit donations: (1) we believ donors obtain a priceless psychological reward by acting as "heroes"; and (2) we generally limit such donations to close family members (and the law traditionally respects "private" family decisions at least where the effort is to save life).[6]

It should be noted. of course, that the autonomy argument does not apply to children, prisoners, or the mentally impaired. and Even if a system of sales is approved for competent adults, none of these individuals should be permitted to consent to sale because of their presumed incompetence or the involuntary nature of their consent and no one should be permitted to consent on their behalf because of the potential conflict of interest involved and the near impossibility of such a sale being in their best interests.[7]

(C) Arugments Against Present Sale

There have been many arguments made against a market in organs, including a dilution of altruism, a less dependable product, the pricing of a priceless gift, the tendency to view human body parts as commodities that may lead us to view human beings as things, and the general unsavoriness of a market in body parts. All of these arguments have some merit. From a legal perspective, however, there is really only one major argument against permitting a competent adult to sell his or her nonvital organs: sale is an act of such desperation that voluntary consent is impossible. In the words of Professor Bernard Dickens:

> The policy behind legislation prohibiting body-material sales [which exist in a number of Canadian Provinces] is ethical and humane; scientific research and medical education should no longer be pursued at the physical cost of the economically and socially deprived, nor should it exploit the needs of the vulnerable...Equally, the poor should not be induced by money to offer the material resources of their bodies, and to convert their own health into a saleable commodity in the market place of human replacement parts.8

Dickens concedes that we do permit the poor to enroll in disproportionate numbers in the armed forces, and to take on essential but uncomfortable or dangerous occupations for money. But in these cases, benefits accrue to society as a whole, and although the employment choices may be limited, choices are not coerced. One way to look at the question is to ask what risks we would permit an individual to consentto in human experimentation.

We require voluntary consent to human experimentation, and so generally prohibit monetary inducement that is so high as to be potentially "coercive." One problem is that the absolute amount that may induce one person to participate may not move another depending upon their relative wealth and present need. Nonetheless, there are surely some experiments that we would forbid outright, such as permitting one to volunteer to have his hand sawed off so surgeons could experiment with a new method of grafting back on. But are there "valid" experiments that we would approve if no compensation is given to volunteers, but disapprove if a significant payment is made? For example, would we approve of a study designed to test a new method of preserving organs from living donors that required 100 kidneys be removed from healthy donors if the donors weren't compensated but disapprove of the same study if each donor-subject was to paid $10,000 for his or her kidney? If we would, it must be because we believe the $10,000 payment would be a coercive inducement and vitiate the validity of the consent. In analogous situations we no longer permit prisoners to volunteer for risky medical experiments (or apparently, to donate kidneys) because we do not believe that they are in a position to give voluntary consent.

It has, of course, been argued that the coerciveness is equal or greater in the relative donation scenario. This may even be true, but society does not create or sanction the coerciveness of that setting, and denying a relative the right to rescue only adds an additional burden to the already tragic situation.

The argument that sale will only sanction the transfer of organs from the poor to the rich can be at least partly answered by having a governmental agency be the sole purchaser and distributor of organs, with distribution based on a criteria other than wealth or social worth.[9] The poor, however, will still likely serve disproportionately as sources of kidneys, and this would likely change only with a more equitable income distriubtion.

II. SALE OF ORGANS OF DECEASED (BY BRAIN DEATH CRITERIA) BY NEXT OF KIN

(A) Present Law

The writers of the Uniform Anatomical Gift Act (UAGA) which is law in all 50 states, made a purposeful decision not to codify the question of sales.[10] Only Delaware has dealt with the issue exolicitly by outlawing remuneration for executing an organ donor document.[11] Some states, like Massachusetts, have statutes that forbid "trafficing" in dead bodies that could prevent sales. Under common law, based itself primarily on ecclesiastical law, one could not have a property interest in a dead body. Instead, the next of kin's interest in the body was limited to an interest in giving it a "decent" burial. It was precisely because of the use of body parts for transplantation had no historical precedent that the UAGA was seen as necessary in the transplant age. It controls with regard to the wishes of the deceased and the deceased`s next of kin, but is, as mentioned, silent as to sale. While the issue could be clarified by judicial interpretation, most commentators believe that statutory formulation is necessary if sales are to be encouraged.[12]

(B) Arguments in Favor of Permitting Sale

The major argument in favor is that it would increase the supply of organs by inducing those few (20-30%) families who are now approached to "donate" their loved one's organs, and refuse, following a determination of brain death, to sell them. It can also be argued that since everyone else involved in the removal of the organ from the deceased (except the deceased's physician) is compensated, the deceased's estate should also be compensated.

(C) Arguments Opposed to Sale by Next of Kin

The major argument opposed to permitting such a sale is that it might give the next of kin a financial motive to help hasten the death of the organ source. At least, it could taint the participation of the next of kin in medical decision-making surrounding treatment decisions. It also raises visions of Coma, and so could turn the public against organ transplantation so much as to actually decrease the total number of next of kin who would be willing either to donate or sell organs. More unlikely, it could result in some hospitals and/or physicians putting a lien on the body and demanding sale so that their bills can be paid in cases involving poor or underinsured patients. Ultimately, "presumed consent" or compulsory removal proposals (which I do not support) would obtain more organs, more cheaply and efficiently, with little more public revulsion or opposition.[13]

II. SHOULD FEDERAL LAW OUTLAW SALE?

The law governing medical treatment, consent, definition of death, donation of organs, autopsy, burial, and the disposition of dead bodies is exclusively state law. Unless there is an extremely compelling justification, it seems unreasonable and unnecessary for the federal government to legislate in this area. Further, it is unclear precisely what authority the federal government has. The proposed National Organ Transplant Act, for example, proposes to outlaw sales of human organs when the "transfer affects commerce." "Commerce" is defined as "trade, traffic or transportation between a place in a State and any place outside thereof or which affects such trade, traffic, or transportation." This is broad language, and consistent with federal authority under the Food, Drug and Cosmetic Act. On the other hand, transplants may not involve organs moving across state lines; and that if they do, and if the organ is not removed from the vendor until after he moves across state lines, the law may not reach the transaction. Even if it does, however, dealing with organs under the commerce clause seems to concede that organs can properly be viewed as objects of commerce.

Since essentially all kidney procurement in this country is directly financed by the federal government, it would seem more appropriate for the Congress to forbid any reimbursement for procurement or transplantation of an organ which was obtained by paying the vendor ("donor") or the donor's next of kin.

DRAFT

NOTES

1. They are: (1) a present contract for the right to the body upon death with remuneration to be paid to named beneficiaries and the amount ascertained upon death; (2) a present contract for the right to the body upon death with remuneration to be paid to named beneficiaries upon death for a specified amount; (3) A present contract for the rights to the body upon death with present payment to the seller; (4) present transfer of a nonvital organ for money; and (5) sale by the next of kin of decedent's body parts after death. Note, The Sale of Human Body Parts, 72 Mich. L.Rev. 1182, 1218-19 (1974).

   (1)-(3) have extremely limited application since most organ removals require either a live body or one maintained on a mechanical ventilator that has been pronounced dead on the basis of brain death criteria.

2. The crime has, however, been found applicable to a physician who aided in the amputation of an individual's fingers so he could collect insurance by "deadening his fingers by hypodermic injection." State v. Bass, 255 N.C. 42 (1961)

3. See, e.g., Dukeminier, Supplying Organs for Transplantation, 68 Mich. L. Rev. 811, 853-857 (1970).

4. Dickens, The Control of Living Body Materials, 27 U. Toronto L. Rev. 142, 165 (1977).

5. Fitzsimmons v. N.Y. Supp.111 (1914); Contra., American Motorcycle Assoc. v. Dept. of State Police 11 Mich. App. 351 (1968, (motorcycle helmet law unconstitutional because it is

"stretching our imagination" to find a relationship between it and the public health, safety and welfare).

6. If we permit a father to donate his kidney to his wife or child, however, it is difficult to justify not permitting him to at least trade his kidney for another (directly or through a brokerage firm) in the event that his tissue is not a close enough match for the transplant since in this case the quality of the consent, and the risks undertaken, and the motivation will all be identical.
7. For a discussion of the kidney and bone marrow cases involving children see Annas, G.J., Glantz, L.H. and Katz B.F., "Research with Children: Legal Incapacity and Proxy Consent" in Informed Consent to Human Experimentation (Ballinger, Cambridge, Ma., 1977) at 63-101 (portions attached as Appendix A).
8. Dickens, *supra*. note 4 at 166.
9. Id. at 168 and See, Note, *The Buying and Selling of Human Organs from the Living: Why Not?* Akron L. Rev. 152, 168 (1979).
10. *Sale of Human Body Parts, supra,* note 1 at 1191.
11. 24 Sec. 1783(f) of Delaware's "Uniform Anatomical Gift Act" provides, "A person who so directs the manner in which his body or any part of his body shall be disposed of shall receive no remuneration or other thing of value for such disposition."
12. See e.g. Brams, *Transplantable Human Organs: Should Their Sale Be Authorized by State Statutes?* A.J. Law and Med.

Sale Be Authorized by State Statutes? A.J. Law and Med. 183, 194 (1979); and Note, *Retailing Human Organs Under the Uniform Commercial Code,* 16 John Marshall L. Rev. 393, 407 (1983).

13. See Dukeminier, *supra,* note 3 at 837-842.

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APPENDIX A

Informed Consent to Human Experimentation:

The Subject's Dilemma

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In summary, certain points can be made regarding how courts view parental and children's rights to make decisions concerning risk-taking.

1. The general rule concerning majority and the age of consent is not based on a scientific or logical rationale. It is the result of generally irrelevant feudal law doctrine.
2. Parents can consent to therapeutic medical care for their young children.
3. The trend is that older children who can understand the consequences of a therapeutic medical procedure can consent to that procedure.
4. In the area of consent to therapeutic medical treatment courts require either the consent of the minor or of the parent, but not of both.
5. In areas outside the field of medical treatment, courts find that children may consent to take risks or waive rights, but base their decisions on the factual circumstances of the specific case.

NONTHERAPEUTIC EXPERIMENTATION ON MINORS

It has been stated that a resolution of the legal problems surrounding nontherapeutic experimentation on minors is made extremely difficult due to the fact that statutory law is nonexistent and case law is largely irrelevant.[84] Unfortunately, this observation is correct. Two questions are presented that must be dealt with. First, since it is generally understood that the law allows a parent to consent to the invasion of his child's body only if such invasion is for the child's benefit or welfare,[85] can the parent consent to the conducting of nonbeneficial experimentation on the child? Second, at what point must the child give his consent (or assent) to a nontherapeutic procedure as a precondition to its performance?

In trying to answer these questions, Professor Paul Freund has explained how the law approaches novel questions.[86] Law is a basically conservative field—no Nobel Prize is awarded for the most revolutionary judicial decision of the year. The law fears setting a bad precedent. To expand on this point Freund cites F.M. Cornford's book, *Micro-Cosmographia Academica* where it is stated in a somewhat tongue-in-cheek fashion:

> The principle of the dangerous precedent is that you should not now do an admittedly right action for fear that you or your equally timid suc-

> cessors should not have the courage to do right in some future time, which *ex hypothesi* is substantially different but superficially resembles the present one. Every public action which is not customary is either wrong or, if it is right, is a dangerous precedent. It follows that nothing should ever be done for the first time.[87]

Law also tends to generalize on the basis of balancing risks and is deeply protective of human integrity and life. Finally, law is creative and responsive—if the reason for a rule of law ceases to exist, the rule of law should also cease to exist.[88]

With this as a background, we can examine how the problems set forth above have been dealt with.

Codes of conduct that are often referred to for guidance in this area of human experimentation do not directly confront this issue. The Nuremberg Code's first principle is that:

> The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[89]

As the previous examination of the law has demonstrated, minors are generally deemed legally incapable of giving their consent to medical treatment. For emancipated and mature minors, courts and legislatures have decided that they may consent to medical treatment that is rendered for their benefit. It is not all clear that such minors could consent to nontherapeutic procedures. But assuming that minors are legally competent to give such a consent, they must have "knowledge and comprehension of the elements of the subject matter involved" in order to give such consent. This sounds very much like the mature minor rule discussed earlier. Some argument could be made that under the Nuremberg Code, older minors can and must consent to nontherapeutic research in order for such research to be conducted on them.

It also appears that the Nuremberg Code outlaws proxy consent. It is the consent of the "human subject" that is required, not the consent of a guardian or representative.

The Helsinki Declaration, on the other hand, states that a subject must give his free consent, but "if he is legally incompetent the consent of the legal guardian should be procured."[90] It is not clear, however, whether or not the guardian's consent is in addition to the incompetent's consent, or if it acts as a substitute for the subject's consent.

* * * * *

In the English view one cannot perform nontherapeutic procedures that involve risk on any minor under the age of twelve, or on any minor over the age of twelve, unless he can give "true consent." In cases in which such consent is obtained, parental consent is not required by law, although it might be prudent and ethically desirable.

In a limited way the Michigan legislature had adopted a variation of this rule. Section 27.3178(19b) of the Michigan Code states:

> A person of fourteen years of age or older may give one of his two kidneys to a father, mother, son, daughter, brother, or sister for a transplantation needed by him, when authorized by order of the probate court. . . .
>
> If the court determines that the prospective donor is sufficiently sound of mind to understand the needs and probable consequences of the gift to both the donor and donee and agrees to the gift, the court may enter an order authorizing the making of the gift.

Thus, the only determination the probate court must make is whether or not the minor can give "true consent" to the procedure. If he can, then the minor will be allowed to consent and the transplant can go forward. There is no mention of the need for parental consent, and the statute would seem to ban organ donation by younger children. This procedure has one advantage over the English rule. In England it would appear that the determination of the existence of a valid consent would occur after the experiment had been performed, whereas in Michigan the before the fact determination better protects all the parties involved.

One transplant surgeon has adopted elements of both the English rule and the Michigan statute. He does not use children under the age of twelve as kidney donors because they are too young to understand the possibility of physical and psychological harm to themselves in the future and are unable to evaluate the present and future state of their health. However he believes children in their teens are acceptable to use as kidney donors.[102]

THE KIDNEY AND BONE MARROW TRANSPLANTATION CASES

The Michigan statute is the result of the existence of a body of case law that deals with the problems of organ transplantation in a confusing and ambiguous manner. Although, as discussed below, these cases are not strictly analogous to the nontherapeutic research situation, they do offer some insights into how courts tend to resolve the issue of proxy consent to nonbeneficial procedures.

Kidney transplantation has been conducted with adults since 1954, with the first case involving minors arising in 1957.[103] This case[104] involved nineteen-year-old twins. Although the healthy twin, Leonard, and his parents consented to the procedure, the physicians refused to operate because of the uncertainty concerning the validity of the parents' and the minor's consent to undergo a surgical procedure not for his benefit. To resolve this problem, an action for declaratory judgment was brought before a single justice of the Massachusetts Supreme Judicial Court. During the hearing, psychiatric testimony was offered to the effect that if the sick twin, Leon, died, it would have a "grave emotional impact" on the healthy twin. A finding was made that the operation was required to save the life of Leon and that Leonard had been fully informed and understood the consequences of the procedure and consented. Unfortunately, the court did not stop here and specifically adopt the mature minor rule in this situation. Instead, it went on to find that the emotional disturbance resulting from his brother's death could affect the health and emotional well-being of Leonard for the rest of his life. Therefore the operation was

> necessary for the continued good health and future well-being of Leonard and that in performing the operation the defendants are conferring a benefit upon Leonard as well as upon Leon.[105]

By finding "benefit" to Leonard, the court was able to circumvent the hard issue, since if the healthy donor received a "benefit" the validity of parental consent would no longer be a problem.

This "benefit" theory was used two more times the same year in cases that involved kidney transplants between fourteen-year-old identical twins.[106] In both of these cases the court found that the fourteen-year-olds understood the probable consequences and risks of the procedures, and gave their consent free of pressure or coercion. But the court still went on to use the psychological benefit theory, thereby avoiding the true issue. In all these early Massachusetts cases the courts found that the minors consented, the parents consented, and there was psychological benefit to the donor. If any one of these elements was missing the outcomes might have been different.

Several cases concerning kidney transplants between siblings have arisen since 1957. Perhaps the most discussed is *Strunk v. Strunk*.[107] In this case the donor, Jerry Strunk, was not a minor but a twenty-seven-year-old incompetent with an I.Q. of 35 and a mental age of six, who was committed to a state institution. The donee, Tommy Strunk, was twenty-eight years old, married, employed and a part-time university student who was suffering from chronic glomerulus nephritis. No other member of the family qualified as a donor due to blood type incompatibility. Because of the apparent lack of benefit to Jerry a court action was instituted, and a guardian *ad litem* (a guardian appointed for the purposes of litigation) was appointed. The guardian questioned the authority of the state to approve the transplant. Psychiatric testimony was offered that alleged Tommy's death would have an "extremely traumatic effect"[108] on Jerry, and that "Tom's life is vital to the continuity of Jerry's improvement"[109] at the state hospital. The court also found that renal transplantation was becoming relatively common and that over 2500 transplants had been done up to the date of the trial. It found that the chances of the transplant being successful increase when the donor and donee are genetically related and that the risk of transplantation to the donee is small, 0.05 to 0.07 percent. The court then adopted the doctrine of "substituted judgment" in which a court acts in a manner it believes the incompetent would act if he had his faculties. The seriously divided court (4-3) allowed the transplant to go forward, becoming the first case in which such an operation was done without the consent of the donor.

In a strong dissent Judge Steinfeld stated "My sympathies and emotions are torn between a compassion to aid an ailing young man and a duty to fully protect unfortunate members of society."[110] The dissenters, recalling the experiments in Nazi Germany found that guardians must act to "protect and maintain the ward."[111] They found that opinions concerning psychological trauma are "most nebulous," that it is well known that transplants are frequently rejected, and that the life of the incompetent is not in danger but that the surgical procedure creates some peril.[112] According to the dissenters, the ability to fully understand and consent is a prerequisite to the donation of a body part and a transplant should not be done on an incompetent until it can be "conclusively demonstrated that it will be of significant benefit to the individual."[113]

Several years later the case of *Hart v. Brown*[114] was decided in Connecticut. This case dealt with a kidney transplant between identical twins who were seven years, ten months old. The court found that although Kathleen, the sick twin, was undergoing regular hemodialysis, she could not do so indefinitely and a kidney transplant was required to sustain her life. It also found that, since immunosuppressive drugs would not be required because the twins were identical, such a transplant would be much less risky for Kathleen than a transplant from a different donor, and that there was substantially a 100 percent chance that both twins would live out a normal life upon following the procedure. The family's clergyman felt the decision was morally and ethically sound and a psychiatrist found that a successful operation would be of "immense benefit to the donor in that the donor would be better off in a family that was happy than in a family that was distressed. . . ."[115] The donor was informed of the procedure and "insofar as she may be capable of understanding"[116] desired to donate her kidney. The guardian *ad litem* also consented. The court specifically noted the limited value of the psychiatric testimony but instead found that

> [i]t would appear that the natural parents would be able to substitute their consent for that of their minor children after a close, independent and objective investigation of their motivation and reasoning. This has been accomplished in this matter by the participation of a clergyman, the defendant physicians, and attorney guardian *ad litem* for the donee, and indeed, this court itself.[117]

It was also found that this procedure was not "clinical experimentation but rather medical treatment."[118] The court held that

> natural parents of a minor should have the right to give their consent to

> an isograft kidney transplantation procedure when their motivation and reasoning are favorably reviewed by a community representation which includes a court of equity.[119]

The right to consent on behalf of a minor was given to the parent as long as the parents' motivation was proper.

In a Georgia case, the court substituted its judgment for a moderately mentally retarded fifteen-year-old girl who was to serve as a donor for her dying mother, and permitted the transplant.[120]

There are two recent cases in which organ donation by a minor was not permitted. In the first, *In re Richardson*,[121] the prospective donor was a seventeen-year-old mental retardate with a mental age of three or four, and the prospective donee was his thirty-two-year-old sister, Beverly. An examination of the court's use of the facts in this case is instructive. It found that although a kidney transplant would be beneficial, it was not immediately necessary to preserve Beverly's life. In the first place, there was evidence that she could be sustained indefinitely by kidney dialysis. Second, although Roy would be the best donor available, as there was only a 3-5 percent chance of rejection with his kidney, there were other donors that could donate with a 20-30 percent chance of rejection. And if these were rejected, other transplant procedures could be done. Thus, a transplant from Roy might be the best alternative for Beverly, but there were other, if less desirable, options open to her. The court discussed the *Strunk* case but found that Louisiana law differs from Kentucky law in that the law of Louisiana "is designed to promote and protect the ultimate best interests of the minor."[122] Under Louisiana's statutes, a minor is not allowed to make any *inter vivos* transfers of property and a parent is absolutely prohibited from transferring a minor's property. The court reasoned that if the law affords such protection against intrusion into a "comparatively mere" property right, it was inconceivable that the minor's right to be free from bodily intrusion would be any less protected.[123] The argument that Roy would benefit from the procedure because Beverly could care for him after his parents died was rejected as "highly speculative . . . and highly unlikely."[124] The fact that the transplant was the most desirable course of action for Beverly was not enough to convince the court of equity to permit the transplant, since less detrimental alternatives were available. But from the legal analysis performed by the court, even if a transplant from Roy was the only way to keep Beverly alive, it would not have had the authority to permit such a transplant.

In the second case, the Wisconsin Court resolved the problem in a similar manner. In this case, *In re Pescinski*,[125] a petition was filed with the court asking it to permit a kidney transplant from Richard, a thirty-nine-year-old catatonic schizophrenic who had been institutionalized for sixteen years and who had a mental age of twelve, to his thirty-eight-year-old sister who was the mother of six minor children. The physician involved said he would not use her parents, who were aged seventy and sixty-seven, since "as a matter of principle"[126] he would not do the operation on a person over sixty. The physician also refused to use a kidney from any of her minor children as a matter of his "own moral conviction."[127] Another brother forty-three-years-old who owned a dairy farm and had ten children refused to be a donor because there would be no one to take care of his farm. Additionally, he said he had a stomach problem that required a special diet, and a rupture on his left side. The court's opinion implied that there were a number of competent, healthy potential donors, who were excluded for "moral reasons" or for personal reservations, and who were not asked or did not volunteer to donate their kidneys because of the existence of Richard.

The court held that since Richard did not consent to the procedure, it could not be done.[128] Additionally, a guardian must act "loyally in the best interests of his ward"[129] and there was absolutely no evidence here that any interests of the ward would be served. The concept of substituted judgment was forthrightly rejected.[130] In summarizing its opinion the court stated:

> An incompetent particularly should have his own interests protected. Certainly no advantage should be taken of him. In the absence of real consent on his part, and in a situation where no benefit to him has been established, we fail to find any authority for the county court, or this court, to approve the operation.[131]

Following this line of kidney transplant cases, a separate but similar line of cases resulted from the advent of bone marrow transplantation procedures.[132] The bone marrow cases provide less of a physical intrusion into the donor's body as no body cavity is opened, and unlike kidneys, the bone marrow regenerates itself. The donor is subjected to as many as 200 aspirations of the pelvic bone with a needle specially designed to remove bone marrow.[133] The Attorney General of the state of Washington has determined that written consent of the guardian is sufficient to authorize a bone marrow donation by a minor.[134]

The practice in Massachusetts, however, is still to acquire a court decree prior to the transplant. The court that created the "psychological benefit" mischief is currently dealing with the problem in a more straightforward manner. Thus in *Rappeport v. Stott*,[135] a bone marrow transplant case, the judge held that a seventeen-year-old was "capable of consenting to the proposed procedure," and did not bother to find that he received psychological benefit.

The most illuminating bone marrow transplant case is probably *Nathan v. Farinelli*,[136] because of its forthright approach. Toni Farinelli was a healthy six-year-old and her ten-year-old brother, William, was suffering from aplastic anemia, which, left untreated, is fatal in eighty-five percent of the cases. The parents consented to a bone marrow transplant but the physicians refused to operate in the absence of a court authorization. The court found that the risk to Toni was minimal, but also found that she would receive no benefit. The petitioners took the standard approach and called a psychiatrist as a witness. Surprisingly, she testified that she would be speculating if she ventured any opinion about the psychological effect of either allowing or preventing the intended donor from furnishing the bone marrow.[137] The court appreciated her honesty and found that

> [t]o require a finding of benefit to the donor, and particularly to accept a psychological benefit as sufficient, often seems to invite testimony conjured to satisfy the requirement by words but not by substance.[138]

The court also rejected the "substituted judgment" theory as being irrelevant in these situations.[139]

> It is the court's opinion that a better approach to the issue involved in this case is to consider that the primary right and responsibility for deciding the delicate question of whether bone marrow should be taken from Toni and transplanted in William is that of the parents with reference to both children.[140]

The requirement that the parents' decision be reviewed arises out of the possible conflict between the parents' responsibility for the care and custody of one child, and their similar responsibility for the other. In what can serve as a summary of all these cases, the court wrote, "It would be more truthful to recognize that the parents themselves are making decisions for their children,"[141] and are not substituting their judgment for that of the child. Finding that the parents' decision was "fair and reasonable" the court permitted the procedure to be done.[142]

The reason for setting out these cases so extensively is that, with the exception of *Bonner*, they are the only cases that deal with consent to nonbeneficial procedures. But we can learn a number of lessons from these cases, as diverse as they may be, that are applicable to research conducted on children.

Although never explicitly stated, courts will permit parents to consent to therapeutic research on children, even where the risks are high, if the benefits are great. In the bone marrow transplant cases, the transplanted bone marrow might cause adverse reactions in the recipient's body. This condition, called graft-versus-host disease, can lead to an agonizing death.[143] However, since the experimental procedure might save the life of a doomed child, no question is raised as to the ability of the parent to consent on his behalf.[144]

As to these cases' importance in regard to nontherapeutic experimentation, we must look at the differences between the transplant cases and nontherapeutic research. First, the procedures that were performed on the donors in the transplant cases were not experimental. Neither the removal of a kidney nor bone marrow aspiration is considered an innovative procedure.

Second, in the average nontherapeutic research setting, parents will not have to struggle with the conflict of interest problem. One commentator has pointed out that one reason why experimentation must be more closely regulated than therapy, is because during therapy the doctor sees the patient as an end and not a means, and in nontherapeutic experimentation the subject is seen as the means and not the end.[145] In the transplant cases the parent must also view the donor child as a means, and the cure of the ill child as the end. As a result, the parent's role as the protector of the donor child might be negatively influenced. Courts should be especially aware of this in cases in which the donor is mentally ill or retarded and it may be suspected that parents and physicians may not value the life of the donor as highly as the life of the donee. This is made all the more apparent by the fact that in all the transplant cases involving mentally ill or retarded adults or children, all the mentally ill or retarded individuals were donors, never recipients. Indeed, during the hearings in the *Strunk* case, the Director of the Renal Division, University of Kentucky Medical Center, testified that if something should later happen to the retarded donor's remaining kidney, based on selection criteria at the Medical Center, the donor would not be eligible for either hemodialysis or transplantation.[146] Because of the possibility of exploitation, it is not surprising that the two cases in which the courts denied permission to conduct the transplant involved a mentally retarded and a mentally ill individual.

In the absence of such a conflict, parents should be better able to protect the interests of their child when an investigator asks their permission to use their child as a subject in nontherapeutic research. It might be presumed that parents could put all their energies into protecting their healthy child, because they need not be concerned about the welfare of a sick child.

Both parents and children might be better able to make protective decisions concerning the child's welfare in nontherapeutic research than in the transplant situation because no duress should exist. When a transplant is needed by a sick child, and the healthy child is the only available donor, one essentially communicates the point to both the parent and the child that unless consent is received from all concerned, the child or sibling will die. Truly voluntary consents are hard to imagine in such a situation.[147] But where neither the parent nor child receives any benefit, duress should be entirely absent.

From this analysis it would appear that children involved in nontherapeutic research need *less* outside protection than transplant donors.

But if one looks behind the logic involved in these cases one can see why these cases are resolved the way they have been. The transplant cases revolve around the power of the family to protect its own members. When a child is sick the family as a unit is permitted to use its resources and make sacrifices to help the sick member. All the courts agree on one point, however—the general rule is that parents must act in the best interests of their children and not subject them to harmful situations. The courts that permit transplants have gone through incredible feats of mental gymnastics, such as finding benefit where none exists, to overcome the general rule. The *Farinelli* case, tired of these maneuvers, directly confronted the issue and held that the family could protect its members, and made its decision on that basis.

In addition, as discussed above by Freund, in the transplant cases the courts are balancing risks and being deeply protective of life. Where the risks are relatively minimal and a life hangs in the balance, the courts will decide in favor of life.

* * * *

CONCLUSIONS AND RECOMMENDATIONS

Therapeutic Research • Where research is designed to cure a specific disease or condition from which the child is suffering, and no other drug or procedure is available to treat such condition or disease, or the existing procedure is more dangerous or produces greater discomfort than the proposed procedure, such therapeutic research should be allowed to be conducted with the informed consent of both parents, or one parent if both are not available.

In such a case the parents are consenting to therapy. Or to put it another way, they are consenting to a procedure that is carried out with the purpose of furthering the best interests of the child. As such, the law will enable parents to consent to such procedures. Although the consent of one parent would probably be sufficient, because of the experimental nature of the procedure it would be prudent to allow both parents to decide that the standard procedure is not to be used, since the new procedure might not be efficacious.

Nontherapeutic Research • For nontherapeutic research that carries a risk of harm, such procedures should only be done when the risks are extremely small and the benefits to society are very great. When it has been determined that the risk-benefit ratio of a certain procedure falls into this category, courts, performing their own balancing test, would probably uphold the parental right to consent to their child's participation in such a study. What constitutes a high-risk procedure is not readily determined. Is a high-risk procedure that which has a one-in-a-million chance of causing death, or one that has a fifty percent chance of causing a headache? Though no definitive answers are available, the Ethical Review Board, the Institutional Review Board and the Consent or Protection Committees should all be given the authority to make an independent determination of this issue regarding any proposed research.

When a minor is capable of understanding these procedures his consent should also be required. Or, in other words, he should have the absolute right to refuse to participate in such nontherapeutic procedures. The problem is setting an age at which a minor has such understanding of risk-taking, benefits and harm, and is able to weigh these factors, so that he can give a truly informed consent. One can establish a subjective rule and say that a minor of sufficient intelligence and maturity to understand the consequences of the proposed experimental procedure may consent to such procedures. Investigators would probably be unhappy with this because they would have to make such a determination, and if they are wrong, liability might result. However, investigators must also make this determination in adults. If an adult is incapable of understanding the risks inherent in undergoing an experimental procedure, an investigator cannot get his informed consent.

Alternatively, one could have all minor subjects of this type of research screened by a protection committee which would make the determination. Or we could ask the courts to make such a finding, as is the case in Michigan in regard to kidney transplants.

The advantage of setting a specific age at which a child can participate or refuse to participate is its objective nature. But it must not be set too low. Draft proposed federal regulations state that research cannot be done on a child above the age of six without his consent.[180] A child of this age will probably agree to do almost anything an authority figure requests. Although it gives the child the right to say no, it is probably a right that will not be forcefully exercised. The age should be set higher, hopefully on a scientific basis with the help of experts in child development. The Michigan statute uses the age of fourteen, Professor Curran suggests fourteen,[181] and the British Medical Research Council suggests twelve.[182]

The consent of both parents should be required if both are alive. Since their child might be injured, they should be able to veto his decision since such an injury would have a negative impact on them and would not benefit their child in any way. In addition, since it can be presumed that they will protect the interests of their child when no conflict exists, their counsel should be sought, and their protective role utilized. Children who have no parents and institutionalized children should not be allowed to participate in such studies. The institutionalized child has the duel burden of his minority and the effects of institutionalization.

Children below the age of consent that have been selected, or who are too young to understand the nature and consequences of a procedure, may be subjects in nontherapeutic research when there is no chance of harm occurring, or, as discussed above, the risks are minimal. When harm cannot occur, the need for consent declines considerably, and one need not worry about the exploitation of the child. Of course, the consent of the parents should still be required.

Federal regulation of research can only add to the protections already required by state law. Thus, if California outlaws all nontherapeutic research on minors, federal regulations cannot permit such activities in that state.

We believe these recommendations are fair. They protect the children-subjects as well as the parents of these children, but do not unduly burden the research community. Such regulation of research will permit it to continue without exploiting the children who deserve our utmost protection.

REFERENCES

Mr. Gore. Thank you very much. I'm going to hold up on questions until the panel is over with.

Let me ask all of our witnesses to summarize the remaining statements as much as possible because of the time constraints.

One of the essential elements in analyzing the ethical consequences of this proposal is—has to do with the medical consequences of a nephrectomy. Dr. Barry Brenner, our next witness, is from Harvard University Medical School and has only recently completed the most up-to-date analysis of what those medical consequences are.

Dr. Brenner, we are delighted to have you here. The subcommittee has had an opportunity to work with you in the past on the diet-kidney disease link, and we appreciate your expertise in a number of fields. Please proceed with your statement.

Dr. Brenner. Thank you, Congressman Gore. It's a pleasure to be here, a privilege.

What I thought I would do, rather than submit or read lengthy testimony, is review with you a few slides that go right to the heart of the issue, if I may.

Mr. Gore. All right.

Dr. Brenner. I don't think all the lights have to be off, and if I don't entrap myself I can proceed.

Forgive me if I overstate my bounds, but I thought it would be useful for this discussion to review with you a little bit about what the kidney looks like and how it works and how it might be affected adversely by loss of some of the tissue that we call kidney tissue.

This is a slide—a microscopic slide magnified about 400 times of essentially normal kidney tissue. It displays two populations of elements in the structure: A background of the structures we call the renal tubules and a few isolated islands of tissue that are really capillaries.

They differ in structure from the bulk of the renal tissue. These capillaries are the smallest blood vessels in the kidney, and their smallness is important. At the level of these capillaries, a driving force of pressure, generated by the pumping action of the heart, causes the movement of fluid from inside the capillaries to this space surrounding the capillary.

This is the proximal most, the earliest portion of the renal tubule system, which you see in abundance. The filtration of fluid that takes place here proceeds in you and me at a rate of about 150 liters per day. The tubules operate on that filtrate, as the filtrate marches through the various convolutions that you see, and reclaims all of the essential nutrients, most of the salt and most of the water, and the amount of urine we all elaborate a day is a very small residuum of two very large processes. About 150 liters of filtrate are being formed, and about 149 liters of fluid are being reclaimed back into the recirculation. The small difference is the nitrogenous waste and the fluid needed to convey that waste out of the body.

This is, for all intents and purposes, normal in appearance except for this area which is clearly abnormal and which would, on a renal biopsy from an individual, constitute a diagnosis of focal and segmental sclerosis.

Of interest, this is not normal human material or material from a human for any cause. This is the appearance of a kidney from a rat whose only misfortune was that 3 months before we made this slide we removed one kidney and a third of the other. And as a result of removal of renal tissue, we set in motion this process, which is destroying this particular capillary unit.

In the more extreme circumstance, after having removed one kidney and just a little bit of the other, although what we left behind was perfectly normal, 9 months later we transformed the appearance of the kidney into this, which is typical of end-stage kidney disease, and the human equivalent of this—and it is the exact equivalent in human material when we look at it—requires dialysis or transplantation if life is to continue because all of these capillaries have been completely destroyed.

Now, what I'm showing you, then, is that removal of some renal tissue begets the destruction of the remaining tissue. Even though in the first instance all of the tissue that had been allowed to remain was perfectly normal, there is a process set in motion just by loss of renal tissue that destroys the remainder.

The question then is how much renal tissue do we need to remove in order to see this final common pathway of destruction initiated. It's very difficult to know, but the reason why I have strong medical reservations about recommending widespread or wholesale commerce in the trafficking of kidneys is that the removal of a kidney may not be as benign as we have been led to believe.

The insurance companies offered some expert testimony in the early 1960's when they were sampled, and the question was put to them in the early days of organ transplantation, kidney transplantation, how safe is it for individuals to undergo nephrectomy. The experience then was not from transplantation donors, but there were many, many insured individuals who had lost a kidney for one reason or another.

Two insurance companies responded to the request, the New York Life Insurance Co. and the New England Life Insurance Co. Both ran their computer and other literature searches, data searches, and concluded over the course of a 5-year study that if mortality is the end point, a very easily defined but insensitive end point looking for consequent kidney damage, if mortality were the end point, then there is no greater risk to losing a kidney over a period of 5 years than there is to driving an automobile. Well, I live in Boston, sir, and there's a considerable risk of driving an automobile, as you well know.

This is another way of looking at the question of the impending injury that can befall the kidney with time, in this instance in the presence of two kidneys. Most of us develop various illnesses during life and physicians know about us and render service for them. But a few of us escape over the whole of our lives ever needing the facilities of the hospital or the care of a physician.

In this slide is shown the incidence of damage to these capillaries in the kidney that are called the glomeruli, as I showed you before. The age-related damage to the glomerulus that occurs in perfectly normal individuals—this is a very unique population, was accumulated by Gloria Gallo at Bellevue Hospital. It reflects people who, though perfectly well, one day, with some misfortune, dropped dead on the streets of New York, were taken to Bellevue Hospital, and if a family member came to claim the subject, the deceased, and in response to a question from the morgue personnel in terms of who was Uncle Harry that you are here to claim, if the answer to the question was Uncle Harry ever sick, if the answer was no, then the results that I show you here were accumulated; that is, in perfectly healthy individuals beyond the age of about 50 there is a progressive damage to the glomeruli. There is a process of progressive damage that befalls all of us, even though we are perfectly healthy. There is then loss of kidney function, just as associated with graceful aging.

The function of the kidney, expressed here as the blood flow rate to the kidney, as a function of age, in subjects that are studied repeatedly from youth to old age in the national gerontology longitudinal aging study, where again none of the individuals included are in any way sick, they are excluded from longitudinal study, year after year study, if they have to go to a hospital for any cause, but if they escape the need for medical attention, they are studied. These happen to be mostly retired bureaucrats, and that's why you see so many of them in the upper age group.

Here's a biopsy from a young man who shows the changes in the kidney identical to those I showed you from our rats. This young man was in the military from age 19 to 21, and I assume that means he had normal kidneys, but 6 months ago he developed swelling of his legs and was found to have 10 grams of albumin in his urine. The albumin is caused by these abnormal capillaries.

And when this biopsy was called for and getting him ready for the biopsy, as is routinely done, X-ray pictures were done to examine the appearance of both kidneys. It turned out that he was born with only one kidney. In this one kidney he has developed a process exactly akin to what we see in the rats, who also undergo loss of renal mass, but this is congenital loss of kidney tissue, and from center to center now there is an overwhelming pattern of reporting of what was once thought to be perfectly benign, you could go through life with a single kidney, now the occurrence of what is clearly an abnormality that affects many of these individuals.

Not most, but many have hypertension, was not called upon as being potentially interesting when it was first reported and now we are finding some are more misfortunate. They have not only hypertension but they have progressive renal disease, and many are on dialysis.

All of this is a prelude to our own findings. Housed with all of this information we then felt it appropriate to ask the question, what happens to people who elect to give a kidney or who lose a kidney from trauma or because they have a localized form of cancer which can easily be resected and for which there is no long-term risk if the cancer is removed early, but they walk around with one kidney.

We elected to call upon the many individuals in the registry at the Brigham and Womens Hospital, the place where transplantation was first carried out, and asked—I think we sent a request to 53 of them and got a response from 52. All of the requests that went out said you have had—you have donated your kidney more than 10 years ago, 10 years or more. We were not interested in people in these relatively early years. And we said come back and see us because in the literature there has been no formal study of the effects of organ donation of more than 4 years' duration.

Well, in this slide we are looking at the amount of protein excreted per day, albumin. At the time the donors were examined in consideration for donation, none of them had more than a few milligrams of albumin in the urine. If they had more than 50, we weren't taking the kidney because we weren't sure that there wasn't some underlying disease and, therefore, they could ill-afford to lose a kidney.

So, these people underwent intensive surveillance and were acceptable because of the ethical issue involved: a family member needing a kidney. When we now examined the individuals 10 or more years out, this individual, 28 years, is the first human transplant recipient. You see that very few of them have the same low level of albumin excretion as they had at the time of donation. More commonly there is an increase in this protein excretion with time.

We don't want to biopsy the remaining kidney because of the risk of touching a single kidney, but I for one am concerned that this is the tip of an iceberg; that is, if we go out in time with more and more donors, we may see more and more subtle and perhaps more than subtle evidence of renal injury.

This individual donated a kidney 5 years ago to a nondiabetic sib. Now the donor, shown here by having about a gram of protein in his urine a day, an enormous amount, develops diabetes, and we know that diabetes causes kidney damage, the more so if you have only one kidney, and this man will soon go to dialysis.

Now, this is an exception. I know of six donors in the United States that are now on dialysis, but thousands have donated organs, and I am not prepared on the basis of the evidence at hand to say that we should stop harvesting kidneys from family members who, because of the enormous moral and ethical issue, insist on donating. We have some concerns about how to even prevent this, which are relatively minor intrusions on the lives of the patients.

Intense control of blood pressure, I might tell you that 60 percent of the males in our series have developed high blood pressure following the donation of a kidney. This is current incidents of hypertension, diastolic blood pressure equal to or greater than 90 millimeters of mercury. At the time they donated, 18 percent of them had hypertension. Now it's up to 60 percent. The females at the time of donation, 10 percent had hypertension. Now it's up to 30 percent.

We have tried as best we can to identify suitable control group. They're difficult to come by because it's difficult to think of an appropriate control. But we've looked at age and sex matched inpatients in our hospital who are now being evaluated as potential donors and our incidence of hypertension of men and women is half of what we see in the reference group. And if we take neighbors in the community, matched for age and sex, as all of these are, then you see again much less blood pressure elevation.

Now, having said all this, let me tell you that our findings have not been confirmed in a universal pattern. A downstate medical center in Brooklyn, the same incidence of proteinuria and high blood pressure has been found in donors, so they look like our data.

On the other hand, I believe Dr. Salvatierra and I think a group at the Mayo Clinic have begun to look, and I believe also in Dr. Najarian's program at the University of Minnesota, and they inform me that they are finding much less proteinuria or high blood pressure.

In only a rare circumstance is there evidence of renal failure. I still believe since measurements of blood pressure and urine protein excretion are very simple measurements, that our findings are valid and we stand by them.

Whether this will be the same from community to community we don't know, and we have asked—we have implored physicians and surgeons to bring the patients who have served as donors back to the medical facility for examination because up to now it's really been the actuarial experience from the insurance companies to tell doctors that there is no risk and, therefore, patients needn't be followed with continuous surveillance. We think that's not a good policy, and it remains to be determined how much of medical consequence there is to organ donation.

On the basis of what I have found thus far in the animal studies and what we are finding in these early human studies, we would be adverse to recommending any form of kidney transplantation that exceeds the bounds of the closeness of the family unit, where for obvious family reasons we can still justify a procedure that in many countries has never been allowed.

Living-related organ donor transplantation in many countries in Western Europe has never been carried out because even in that close intimate setting within families there have been ethical issues raised. I don't think we should stop in this country on the basis of the findings we have. We need to study the problem more, but I don't see that this medical evidence should support more widespread, unrelated sale of transplanted organs.

Mr. **Gore**. Thank you very much. That's extremely helpful. We will hold questions.

Our next witness is Dr. Robert Veatch, from the Center for Bioethics at the Kennedy Institute of Ethics at Georgetown University.

Dr. Veatch, we are delighted to have you here. We invite you to proceed with your statement.

Dr. **Veatch**. Thank you. In the interest of time, let me limit my remarks to two areas, and primarily the first.

I wish to speak in favor of H.R. 4080's title III prohibition, and then I would like to point out some of the broader implications of the ethical commitments that underlie that prohibition.

The proposal for marketing human organs: Really they pose two separate problems. First, should potential transplant recipients be able to buy organs; and second, should we recruit so-called donors by offering cash.

It is not clear whether any of the proposed organ marketing schemes would permit those in need of organs to buy them on the open market. That part of the problem, it seems to me, could be solved if medicare was committed to including an obligation to pay for the cost of obtaining organs commercially.

Some comments in the press imply that obtaining organs by cash payment would be legitimate; that is, if the recipients themselves were permitted to pay. Dr. Jacobs, for instance, has been quoted as saying, "If the haves want it, they'll have to pay. If the have nots want it, they'll have to pay, too," implying distribution to recipients on a market basis.

Any scheme that distributes lifesaving organs on a basis of ability to pay is discriminatory and, therefore, in my mind unethical. Human life is not, as one commentator would have it, like beer and pantyhose, to be sold to the highest bidder.

I take it as a core moral rule for this discussion that matters of life and death should not be determined by money. That means that even if organs could be procured by money, they should be distributed on some other basis. To me that means medicare should pay the bill so that all would have a fair opportunity to obtain organs.

Buying organs from consenting, so-called donors I take to be a more complex matter than the question of whether we should permit people to receive them on a money basis. Still, on balance it seems to me even procurement of organs for money from so-called donors should be prohibited.

The arguments in favor of permitting procurement for money I think are rather obvious. It at least first seems to be an effective way of radically increasing the supply of badly needed organs.

On the other hand, it seems to me there are strong reasons, both practical and theoretical, why commercial procurement of organs should be banned. We've heard many of the more practical arguments. Let me just enumerate them.

First, the first practical problem with procurement of organs for money is that, at least based on our experience with blood, the quality of the organs procured will be lower. There will be more of an incentive to mask medical problems and the like.

Second, the second practical problem with legal marketing of organs is that the effect is likely—the effect it is likely to have on society's capacity to be altruistic. It's very doubtful in my mind, as we've discussed earlier today, that a voluntary donation and a market procurement scheme can exist side by side.

My wife has already signed an organ donor card. I would certainly do everything in my power to see that her wishes are followed out. If, however, I was offered several thousand dollars to entice me to concur in her judgment, I would have second thoughts. I might refrain from donating if I were offered money, whereas I am quite ready to donate on her behalf, confirm her donation, if I were asked to do so, for no charge.

Still, at the practical level, this practice of permitting purchase of organs could easily extend to unpaired organs. The free market logic and law that would permit a consenting adult to sell his first kidney would also permit selling of the second one. This would be especially true in cases of a suicidal patient or one who has been diagnosed as having a terminal illness.

Still more likely is the effect on availability of cadaver organs. If it becomes common practice to pay for organs from living persons, one can easily envision a family asking for payment when approached about donation of cadaver organs. In fact, if payment were the only available—were only available when one was alive, this would be a tremendous pressure to sell one's organs before death.

In spite of all of these practical problems, it seems to me none of them raise the really basic issue. As with the plan to distribute organs based on ability to pay, a system that obtains organs through a financial incentive would be unfair to the poor. Presumably they are the group that will be enticed into donating organs, yet they are the ones in the poorest health and most generally in need. We would be running our transplantation system for the benefit of the rich off the backs of the poor.

The problem is more complex than it at first appears. The offer to a poor person to buy one of his kidneys say for $10,000 could be conceived as what is sometimes referred to as a coercively attractive offer. If, however, it is coercively attractive, it must be questioned whether a consent is a free one.

It is difficult, however, to know what to do with offers that are coercively attractive. Clearly not all offers that are coercively attractive are necessarily immoral. Consider, for example, the father who is told that he has the only kidney suitable for transplant to a dying son.

If offered a chance to volunteer to donate to his dying son, many fathers would find that offer coercive, attractively coercive; not necessarily wrong, though, because it is coercive.

In order for a coercively attractive offer to be immoral, it must involve someone who has the capacity to solve the problem at hand by some other means. By this logic, offering a destitute person a large payment for a kidney would be both coercively attractive and immoral if the ones making or permitting the offer had the capacity to deal with the problems at hand in some other way.

In fact, we can as a—we can view society or the Government as the one in a position to decide whether to permit such offers to be made. This society and its government have the capacity both to meet the needs of the poor and to create better voluntary procurement systems.

I am forced to the conclusion that it is, therefore—that it therefore should not permit coercively attractive offers to be made in this case. The toleration of such offers would remove the pressure on society both to meet the needs of the poor and to produce a more effective voluntary organ donation system. It would unfairly leave the poor with a choice between two—between only two unattractive alternatives: living in poverty or selling one's kidney. We should therefore, as is proposed in title III, prohibit both the buying and the selling of human organs.

This conclusion has even more radical implications for the procurement program than we might first realize. The key argument against marketing of organs, if I'm correct, is that matters of life and death should not be determined by wealth and that no one should be permitted to make a coercive offer when he has the power to solve the problem by some other means.

These principles lead to opposition for marketing organs, but they just as surely lead to opposition for a wide range of other market allocation decisions in medicine. More specifically with regard to organ procurement for this country, we accept the responsibility to make sure that enough organs are made available through more voluntary methods of donation.

If I am correct, a true national effort is needed if we are going to avoid a marketplace system for organ procurement. In fact, I am arguing that a marketplace system is morally necessary if we fail to produce an adequate voluntary donation system.

This voluntary procurement system must be viewed as a true public good. Many of the best methods for encouraging mass participation simply can't be managed by the private voluntary sector, and this leads me to a rather radical conclusion.

We are reduced in the voluntary sector to such schemes as promoting procurement through radio commercials or even wearing T-shirts that encourage donation. We need a much more thorough system. The Government is much better equipped to provide this public service than any possible combination of private agencies.

Surely private procurement agencies are especially well equipped to carry out some of the functions related to organ procurement. One must be concerned, however, over why H.R. 4080 in its present form channels such a heavy proportion of the organ procurement effort into the nonprofit voluntary channels.

While only a national center will function within the Government itself, the present bill will eventually provide $22 million per year to private agencies. This is a small amount to pay, something less than 10 cents per person. Yet, one wonders whether parts of the job could not be done more effectively and cheaply by Federal agencies.

Finally, let me make one specific comment with regard to the national center referred to in title II of your bill.

Recent legislation establishing Federal commissions has broken ground in recognizing the principle of a lay majority for such councils, commissions, and committees. Yet, in the council that you've proposed in title II, the majority will be transplantation professionals.

The lay majority principle occurred, for example, in legislation creating a National Commission for the Protection of Human Subjects. This advisory council will be dealing with important matters of public policy. Lay people have important differences in perspective from professionals in organ transplantation. It is hard for me to see why six transplant surgeons need to be included but only three members of the general public.

With these minor qualifications and suggestions, I urge you to support H.R. 4080 and especially its prohibition on the purchasing of human organs.

Thank you very much.

[The prepared statement of Dr. Veatch follows:]

Statement Before the Subcommittee for Investigations and Oversight of the Committee on Science and Technology

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November 8, 1983

Congressman Gore and members of the subcommittee: I am pleased to appear before you today to offer comments on H.R. 4080 and some of the ethical issues underlying the problems it addresses. I shall limit my remarks to two areas. I wish to speak in favor of Title III's prohibition of organ purchases, then point out some of the broader implications of the ethical commitments that underly that prohibition.

THE ETHICS OF MARKETING ORGANS

The proposals for marketing of human organs pose two separate issues: first, should it be acceptable for a potential transplant recipient to buy an organ on the open market thus, in effect, jumping to the head of the line? And, second, should it be acceptable to recruit so-called organ donors by offering cash payments? It is not clear whether any of the proposed organ marketing schemes would permit those in need of organs to buy them on the open market from hospitals or commercial procurement companies. The entire question of having those with means get special priority to receive organs could be excluded from consideration if Medicare's commitment to fund end stage renal failure were interpreted to include an obligation to pay for the costs of obtaining organs commercially. Since all (or virtually all) potential recipients would be funded to obtain such organs, no one (at least no American) would be given a special consideration on the basis of ability to pay.

On the other hand, some comments in the press imply that organs obtained by cash payment would have to be purchased by transplant recipients themselves. H. Barry Jacobs, the most widely publicized proponent of commercial organ procurement, has been quoted as saying, "If the 'haves' want it, they'll have to pay. If the 'have nots' want it, they'll have to pay, too."[1] This implies that a marketing scheme would permit not only procuring organs from "donors" via cash payment, but distributing them to recipients on a market basis as well.

Any scheme that distributes life-saving human organs to recipients on the basis of ability to pay is grossly discriminatory and, therefore, unethical. In a society generally committed to liberalism and the right of individuls to buy and sell goods as they see fit, that conclusion may not be as obvious as it seems at first. Even if we do accept that most commodities can legitimately be sold on the open market, however, human life cannot be reduced to that level. Human life is not, as one commentator put it, like beer and panty hose to be sold to the highest bidder. I take it as the core moral rule for this discussion that matters of life and death should not be determined by money. That means that even if organs could be procured using financial incentives, they should be distributed on some other basis. Medicare should pay the bill so that all would have a fair opportunity to obtain organs. The costs may be high, but if that is what it takes to obtain the organs, it will be worth it. That leaves us with the second question: is it acceptable to procure organs for money?

Buying organs from consenting "donors" I take to be a more complex matter, but still one that, on balance, should be prohibited. The arguments in favor of permitting procurement for money are obvious. It, at least at first seems to be an effective way of radically increasing the supply of badly needed organs. If free and consenting adults decide they would be better off with $10,000 than with a second kidney, who are we to prohibit them from making a deal with a kidney broker? Permitting such a deal would make a group of donors who are presumably very poorly off, better off than they were and would also improve the lives of potential recipients.

On the other hand, there are strong reasons, both practical and theoretical, why commercial procurement of organs should be banned. A first practical problem with legal procurement of organs for money is that, at least based on our experience with blood, the quality of the organs will be poorer. When an organ source is motivated financially, he or she has an incentive to hide potential problems--a history of kidney disease in the family or an existing illness, possibly even a terminal illness, in the contributor.

Another practical problem with a policy of legal marketing of organs is the effect it is likely to have on a society's capacity to be altruistic. It is very doubtful that a voluntary donation system and a market procurement scheme can exist side by side. Richard Titmuss developed this claim with regard to systems for blood procurement.[2] He points out that one is much less likely to be altruistic if one knows that others in the society are being paid to engage in the same act. Thus while in Britain blood procurement is voluntary, in the United States only about ten percent of blood is procured entirely without compensation.[3]

Still at the practical level, the committee should realize that practice of permitting the purchase of organs, unless it is prohibited by Title III of the proposed legislation, could easily extend to unpaired organs. The free market logic and law that would permit a consenting adult to sell his or her first kidney would also permit that person to sell the second one. While it at first seems bizarre that someone might want to sell unpaired organs, certain individuals might be tempted: the suicidal, the terminally ill, and those desperate for resources for their children. One could easily imagine someone diagnosed as having a terminal illness deciding to sell not only both kidneys, but the full range of other organs as well. Without Title III this might be legal.

Other organs are not critical for life and yet might be attractive market place commodities. It is reported that already some hospitals sell human placentas obtained from normal child birth. The market mentality might permit young adults to sell a no longer essential organ. For example, it may be possible to remove human thymus glands in order to manufacturer pharmaceuticals. Would we want people enticed into this surgery out of an offer for payment?

Still more likely is the effect on availability of cadaver organs were it legal to buy organs from living humans. If it becomes common practice to pay for organs from living persons, one can easily envision a family asking for payment when approached about donation of cadaver organs. In fact if payment were only available while one was alive, this would be a tremendous pressure to sell one's organs before death.

In spite of all of these practical problems with a market system for encouraging people to make organs available, none of them raises the really basic ethical problem. As with a plan to distribute organs based on ability to pay, a system that obtains organs through financial incentive would be unfair to the poor. Presumably they are the group that will be enticed into donating organs, yet they are the ones who have the poorest health and are most generally in need. We will be running our transplantation system for the benefit of the rich off the backs of the poor.

The problem is more complex than it at first appears. The offer to a poor person to buy one of his kidneys for $10,000 could be what is sometimes referred to as a coercively attractive offer. If, however, it is coercively attractive, it must be questioned whether the consent is a free one.

It is difficult to know what to do with offers that are coercively attractive. Clearly not all offers that are coercively attractive are necessarily immoral. Consider, for example, a father who is told that he has the only kidney suitable for transplant to a dying son. If offered a chance to "volunteer" to donate to a dying son, many fathers would find the offer coercive, but not necessarily wrong because it is coercive.

Scholars who have worked on the problem of coercive offers have generally concluded that in order for a coercively attractive offer to be immoral it must be offered by someone who has the capacity to solve the problem at hand by some other means. If a physician offered to cure a patient's serious illness on the condition that the patient must volunteer for some dangerous research the offer might be coercively attractive. It would also be immoral since the physican would have it within his capacity to treat the patient without commanding the price. On the other hand the transplant surgeon offering the father the chance to volunteer might well have no reasonable alternative way of solving the son's kidney problem.

By this logic, offering a destitute person a large payment for a kidney would be both coercively attractive and immoral if the one making the offer had the capacity to deal with the problems at hand in some other way. In fact we can view society or the government as the one in a position to decide whether to permit such offers to be made. This society and its government have the capacity both to meet the needs of the poor and create a better voluntary procurement system. I am forced to the conclusion that it, therefore, should not permit coercively attractive offers to be made to the destitute who would be attracted by an offer to buy their organs. The toleration of such offers would remove the pressure on society both to meet the needs of the poor and to produce a more effective, voluntary organ donation program. It would unfairly leave the poor with a choice between only two unattractive alternatives: living in poverty or selling one's kidney. We should, therefore, as is proposed in Title III, prohibit both the buying and selling of human organs.

THE IMPLICATIONS FOR THE PROCUREMENT PROGRAM

This conclusion has more radical implications for the procurement program than are at first apparent. The key argument against marketing of organs, if I am correct, is that matters of life and death should not be determined by wealth and that no one should be permitted to make coercive offers who has the power to solve the problem in some other way. These principles lead to opposition to marketing of organs, but they just as surely lead to opposition to all market allocation decisions in medicine. At least when we are dealing with medical interventions that have life and death implications, we should not permit them to be allocated on the basis of who has money to pay for them. Thus if we conclude, as we should, that organs should not be bought and sold, we probably also must conclude that all other life-saving health care interventions should not be bought and sold. The very same principles that lead us to oppose marketing organs lead us to oppose other market arrangements in medicine and lead us to support a standard, universal health insurance system or health service for everyone.

Moreover, if we accept the conclusion that offers to buy organs from the poor are unacceptably coercive, we simultaneously accept a responsibility to improve their lot and to do what we can to improve voluntary procurement. More specifically with regard to the organ procurement system for this country, we accept the responsibility to make sure that enough organs are made available through the more voluntary traditional methods of donation. The resources are there. Various surverys indicate that between 70 and 80 percent of the population are willing to donate.[4] What is needed is a system for overcoming the inertia most people have leading them to resist actually making the donation commitment. If I am correct, a true national effort is needed if we are going to avoid a market place system of organ procurement. In fact, I am arguing that a market place system is morally necessary if we fail to produce an adequate voluntary donation system.

This voluntary procurement system must be viewed as a true public good. Very few goods in a society are truly public goods. Usually individual efforts can produce good. The government has no business intervening with these private decisions. Those who want the good, will produce it. For a very few goods, however, individual efforts cannot produce the desired social result. It is not really in anyone's interest to produce a portion of the good unless everyone contributes to a corporate effort. This is true of our highway and water systems. It is also true of the military.

The procurement of organ donations is quite different from the procurement of blood, for example. For blood, the private voluntary system works as well as it does because the system need reach only a small fraction of the population for the system to work. For solid, non-replaceable organs, however, virtually every citizen must participate to the extent of deciding whether to donate in order to assure that a large enough pool of organs is available from the small number of people who unfortunately come to be in a position to become donors. Fortunately, not everyone need volunteer to become a potential donor, but everyone or nearly everyone will need to respond to the donation question either positively or negatively. If eveyone who favored donation signed a donor card, enough organs would be available. Neither a marketplace procurement nor compulsory salvaging of organs would be necessary.

Many of the best methods for encouraging mass participation simply cannot be managed by private voluntary agencies. They are reduced to promotion campaigns such as radio commercials and wearing tee shirts that encourage donation. We need a much more thorough system. It must overcome inertia and reach nearly everyone. Moreover, if we listen to the experts on promotion of organ donation, we are told that the system needs to be one that encourages family discussion so that family members will not resist organ removal if the critical moment arrives. Furthermore, the records need to be easily stored in a central information system so that hospitals can quickly check the donation status of potential donors.

The government record systems are much better equipped to provide this public service than any possible combination of private agencies. We could, for example, add a question to the income tax form about donation preference. Virtually all adults would be given a chance to say "yes," "no," or "not sure" to the critical question. It could easily be stored on the IRS computers for rapid retrieval. At least for families filing joint returns when one person who is filling out the return comes to the question about donation, he would be forced to discuss the matter with the spouse.

The same advantages could be obtained by attaching organ donation questions to census forms or social security W-4 forms. They are completed regularly and the information is easily stored. Some of the same advantages are also obtained by attaching the questions to state driver's license forms, but no incentive to discuss accrues, no central records are kept, and in many states people are not really forced to confront the question.

Surely, the private procurement agencies are especialy well equipped to carry out some of the functions related to organ transplantation. They seem to be particularly good at locating and processing organs once they become available. One must be concerned, however, over why H.R. 4080 in its present form, channels such a heavy proportion of the organ procurement effort into non-profit voluntary channels. While only a National Center will function within the government itself, the present bill will eventually provide for $22,000,000 per year to private agencies. That is a small amount to pay for the security of knowing that an organ procurement system is in place and that neither marketing of organs nor direct coercive salvaging will be necessary--something less than ten cents per person. Yet one wonders whether parts of the job could not be done even more effectively and cheaply making better use of federal agencies especially in overcoming the inertia of deciding to donate.

Finally, I wish to raise one more specific concern about H.R. 4080. I note that the National Center referred to in Title II will have an advisory council made up of fifteen people. The movement toward a mix of different professional and lay interets is impressive and important. Nevertheless, I wonder whether there is still not too heavy a representation from professionals directly related to transplantation.

Of the fifteen members, six are to be physicians in fields related to human organ transplantation and two others must represent the field of human organ procurement. That means that the majority are transplantation professionals. In addition, another is to represent health care financing. Thus, nine of the fifteen will come from the health care professions and possibly more will as well.

Recent legislation establishing federal commissions has broken ground in recognizing the principle of a lay majority for such councils, commissions, and committees. That occurred, for example, in the legislation creating the National Commission for the Protection of Human Subjects. The fact of the matter is that this advisory council will be dealing with important matters of public policy. Lay people have important differences in perspective from professionals in organ transplantation.[5] Certainly, some professionals need to be involved, but it is hard to see why six transplant physicians need be included, but only three members from the general public. Professionals in any field are likely to have special value perspectives. They should not be over-represented in bodies that will be making important public policy recommendations.

With these minor qualifications and suggestions, I urge you to support H.R. 4080 and especially its prohibition on purchasing of human organs.

[1] Margaret Engel, "Va. Doctor Plans Company to Arrange Sale of Human Kidneys," The Washington Post, September 19, 1983, p. A-9

[2] Richard Titmuss, The Gift Relationship: From Human Blood to Social Policy, New York: Random House, 1971.

[3] Marc Basson, Ethics, Humanism, and Medicine, (New York: Alan R. Liss, Inc., 1980), p. 127.

[4] For a summary of the data see Jeffrey M. Prottas, "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation," Milbank Memorial Fund Quarterly/Health and Society 61(No. 2, 1983), 278-306.

[5] Although many transplant surgeons reportedly oppose organ procurement by purchase, the one surgeon formally writing on the subject has endorsed commercial procurement. See D.T. Freier, "Organ Selling for Transplantation," in Ethics, Humanism, and Medicine, pp. 141-43.

Mr. GORE. Thank you very much. I appreciate your statement.

Just a point of clarification. You say in your statement that the bill would provide eventually $22 million per year. Actually, that occurs only in the third year.

Dr. VEATCH. That is why I said eventually.

Mr. GORE. Yes; but then after that, then the funding does not continue.

Dr. VEATCH. Yes, yes. Well, my point wasn't so much that that's a large or a small amount. It seems to me that's a small price to pay, but I wonder whether all of that money should be channeled into private agencies when for some of these tasks the Government could do the job much better.

Mr. GORE. OK. We'll come back to that. I just—I wanted to clarify the unintentional implication that this is an annual expense of $22 million a year, because it's not.

Dr. VEATCH. Yes.

Mr. GORE. Let me call now on our next to last witness, Dr. Arthur Caplan, associate for the humanities at Hastings Center. We're really proud to have you here and invite you to proceed, Dr. Caplan.

Mr. CAPLAN. All right. I will be brief, but I don't want my brevity to be confused with the fact that I think ethics is unimportant or deserving of less time on the matter of markets in the area of organs.

Mr. GORE. Rest assured, we agree with you.

Mr. CAPLAN. Earlier the comment was made that what this committee was attempting to do was legislate medical ethics. I might say that I would hope so, and if we're not going to be legislating medical ethics, there's not much to legislate about in medicine.

I will address myself to the ethical reasons that I think we ought to ban the sale of organs. There are really four. They concern supply, the matter of trust between doctor and patient, the issue of quality, and the issue of justice.

I won't accept the allegation that a market is the way to solve the problem in the supply of organs. I think that's an empirical question that is open for discussion. It seems to me there is reason to, in fact, question whether markets will provide us with an increase in supply.

I only would remind the Congressman that the effect of markets in areas such as property access to beachfront has not resulted in the creation of a market in greater access for all Americans to homes at the beach.

There are occasions in which, if you allow a market to exist, you decrease access for others, and there are three very good reasons to assume that if we allowed a market in this area, it would be immoral because we would decrease the supply.

First, very few people would be able to bid competitively for the acquisition of an organ. You'd simply be excluding people who couldn't compete financially.

Second, it's quite likely that the introduction of middleman costs of the sort that Dr. Jacobs was so colorful in describing in his Bangladesh proposals are clearly going to raise the cost of getting organs overall.

Finally, the creation of a market will add an additional cost to the entire transplantation budget. It's simply—to put it simply, you'll have to pay for a lot of what comes in free now, and that will mean that there is less money available for reimbursing transplantation procedures overall.

So, I see no reason to think prima facie that there is going to be an increase in supply or more access for anyone if we tolerate a market. I would suggest, in fact, that ethically speaking it's dangerous and risky to take on a new policy that might, in fact, decrease access to those in need.

On the matter of trust—and I think this is an important area that I haven't heard much about today, but I'd like to say a few words about it—it's a central tenet of medical ethics, a longstanding tradition in ethics within America, that physicians honor the principle of not doing any harm in the course of treating their patients.

Patients simply won't trust their doctors unless they believe that these doctors have their best interest and only their interest firmly in mind in making recommendations to them.

Trust is essential to the practice of medicine. Patients who don't trust their doctors will not seek their care or, if they do, they may not be forthright and open with them. Such distrust, if it is allowed a matter of public policy to enter into medicine, would have a catastrophic chilling effect on medical care.

Yet, this chilling effect is exactly what a market in organs would produce. Could the public really give its trust to a profession whose members are willing to conduct surgery upon them not for their benefit, but for the profits that will accrue to the donor and the doctor?

Recent public outrage over the overutilization of such surgical procedures as hysterectomies, tonsillectomies, and coronary bypass surgery certainly gives an indication of the answer that I think is appropriate to that question.

To allow doctors to undertake major risky surgical operations on living donors for reasons of profit and profit alone is to condone a practice which would totally undermine public trust in the medical profession and which would violate the existing canons of the ethics of that profession.

On the matter of quality, we've heard a lot today about the effects of a market in the whole blood system. Unfortunately, I don't think we have the empirical evidence to know exactly what the effects were of allowing a commercial market to exist in whole blood donation.

The evidence is not, in fact, very clear about whether blood that was donated is superior in quality to blood that was bought, but we do have some more recent evidence that is very real—it's taken place over the past year or two—to see the effect of a commercial market. Those two areas have been with respect to plasmapheresis and sperm banks.

Sperm banks are now publicly airing their concern. Recently an article appeared in the New England Journal of Medicine about the effect that payment may have on the willingness of donors to conceal important facts about their medical or genetic history.

Plasmapheresis centers, the major purchasers of blood in this country today, are now enormously and, I might add, publicly concerned about the incentive payment gives to donors to conceal facts about their sexual practices, practices which may be implicated in the transmission of various viral diseases through blood transfusions.

So, if we are really concerned about maximizing the quality of organs, I'm not sure the whole blood system gives us the information we want. I am sure that there are certainly hard facts within the sperm bank system and within the plasmapheresis network that have come out in the past year to make us really wonder exactly what types of incentives a market gives to somebody to perhaps not be as forthright and honest as they must be if we are going to give quality to those in need in terms of the organs they receive.

As to the last matter of what I termed justice, it seems to me that Dr. Veatch has been fairly eloquent on the point. I'm not going to say much more about the matter of the fact that a commercial market is certainly in reality going to wind up calling upon those who are the poorest and least well off in our society to bear the burden of organ transplantation.

It seems to me that there simply are some practices that we could allow to go forth in this society for money—slavery, the selling of dead bodies, public suicide for the amusement and entertainment of us all—but we ought not tolerate these practices in this society.

While there may exist many people who are desperate enough to sell all or parts of their bodies to others for money, is it really in their best interest to allow them to do so, much less encourage them to do so by a matter of public law? Surely our society can provide better ways for solving the problems of poverty, unemployment, and desperate need than by encouraging people through matters of public policy and law to sell vital organs, or families to parcel out the bodily remains of their loved ones to the highest bidder.

A market in organs may not solve—in fact, I believe would in fact run some risk of increasing—the shortage in the supply available now. Permitting a market would certainly undermine public trust in the medical profession and would jeopardize the ability of physicians to adhere to their longstanding commitment to intervene only in the interest of patient welfare.

Commercial markets would not increase and might lower the quality of organs available for transplant. And I believe, finally, that the sale of organs would encourage those who are the most weak and vulnerable in our society to treat themselves as commodities in the name of short-term profit.

So, for the ethical reasons of supply, quality, trust, and inequity, I believe that you should act and enact quickly H.R. 4080 to ban the sale of human organs for the purpose of transplantation.

[The prepared statement of Mr. Caplan follows:]

ETHICAL ISSUES IN THE SALE OF HUMAN ORGANS FOR TRANSPLANTATION

Testimony presented to the Subcommittee on Investigations and Oversight, Committee on Science and Technology, November 7, 1983.

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During the debate over the passage of the Uniform Anatomical Gift Act during the late 1960s some commentators warned that if the public did not respond adequately to the need for organ donation it was quite likely that proposals would appear urging the creation of a market in solid organs. Sadly, as a result of the all too real shortage of solid organs currently available for transplantation, that day has now arrived. As this committee is well aware, various parties have come forward publicly with proposals both to sell their own organs to those in need, and, to create brokerage services which would act as intermediaries between those in need and those both in this country, and, in other nations who are willing or, more realistically, are compelled by economic necessity, to sell their organs.

Proponents and supporters of this macabre trade argue that such a system can be justified on four grounds;

(1) a market would alleviate the present shortage in organs for transplantation,

(2) commercial markets have proven successful for supplying other biologically useful substances such as blood and sperm,

(3) a market in organs for both live and cadaver donors would help to alleviate the frictions created between health professionals and donors by a voluntary system of organ donation,

(4) a market in organs would improve the quality of organs available for transplantation.

Proponents of commercial markets are well aware that the creation of a market in organs seems morally offensive to many Americans. However, they argue that moral reservations concerning the buying and selling of organs should be given little weight given our society's committment to free enterprise. They note rather sarcastically that those with ethical concerns about the acceptability of a market in organs appear to be inconsistent in their ethical beliefs since there exist many areas of life in which Americans are permitted and even encouraged to follow policies that may pose risks to health or safety in the name of profit and social good.

I believe that those who favor the creation of commercial markets as the best means of alleviating the current shortage of solid organs for transplantation have not made a persuasive case for the efficacy of such a system. Indeed, if this society decides to tolerate a market in solid organs such a decision poses a grave risk of actually increasing the gap between the number of organs that are needed and the number of organs now being transplanted to the many desperate victims of organ failure. Furthermore, there are basic moral values rooted in the commonly accepted ethical, theological and medical traditions of our society which require immediate legislative action by Congress to ban the sale of organs for purposes of transplantation in this country.

Proponents of a market in organs argue that the present shortage of solid organs for transplantation to those in need shows that American lack the altruism and public spiritedness necessary for a volunatary system to succeed. I think such arguments greatly underestimate the generosity, community mindedness and altruistic spirit of the American people.

There is no doubt that a serious shortage of organs does exist. The number of organs recovered from cadavers is much lower than the number that could in theory be obtained from the pool of potential donors. Published estimates by the Center for Disease Control and professional experts in the field of organ transplantation state that organs are recovered from only ten to twenty percent of possible donors.

The shortage is surely real but what in fact are its causes? Many states have failed to pass legislation affirming the irreversible cessation of all brain function as the criterion of death. This legislative failure has made many physicians, nurses and other medical personnel reluctant to become involved in the solicitation of organs from the families of cadaver donors.

Many hospitals around the country will not allow their staffs to procure organs for transplantation because of their uncertainties as to their legal vulnerability to costly suits. Since no one can be altruistic without knowing that the possibility exists of making a gift it is simply wrong to say that Americans lack the will to help those who are medically in need of a transplantation in order to live or to regain vital biological functions.

There are also numerous problems in the organization of our present voluntary system which contribute to the poor yield in organs from cadaver donors. Comprehensive public education as to the importance of organ donation is both difficult and expensive. Many Americans still do not know about the need for organ donation and many health professionals have not been properly educated as to the importance of soliciting organs from the families of those who have unfortunately and often unexpectedly died from a sudden accident or congenital condition. Until a vigorous effort at public and professional education is undertaken by our hospitals, medical societies, schools, churches and government agencies to educate each citizen about the need for donation there is no reason to assume that Americans lack the kind of moral concern necessary to make a voluntary system work.

The fact is that despite the passage of the Uniform Anatomical Gift Act in 1968 this country has not taken the legislative and educational steps necessary to make that system work. There are too many people who still do not understand the need for organ donation, too many private agencies, organizations and groups, involved in inefficient and redundant activities in the organ procurement field, and, too many medical professionals worried about the legal consequences of organ procurement to say that the existing shortage of organs proves that a system based upon free, voluntary and altruistic choice cannot produce the organs needed for transplantation.

Moreover, there are many reasons for doubting whether a commercial market would actual solve the problem of obtaining a sufficient supply of organs. It is true that some individuals might be motivated by the prospect of profit to either sell their own organs or to sell the organs of relatives who have died. However, it is also likely that a market system in organs would produce fierce bidding among those in need. It seems unlikely that a desperately ill or dying person would be able to bargain on an equal basis with a person holding the key to sight, a life free from dialysis, or to life itself in the case of heart or liver transplants.

Markets work best when the parties involved can bargain with one another in good faith as approximate equals. Those dying from various forms of organ failure hardly seem to fit this description. The price they could and probably would be asked to pay is one that would exclude all but the very wealthiest among them. The escalation in the cost of obtaining organs for transplant that a market would surely entail could result in fewer people obtaining transplants. First, because few people would be able to pay the prices necessary to obtain an organ in an open market system. Second, given the increase in overall costs that a market in organs would entail, it is certain that the overall cost of transplant surgery would rise thereby decreasing the number of procedures that are done due to limits on the overall amount of money available for reimbursing the costs of these procedures.

Not only is there no guarantee that allowing a market in organs would increase the supply available for transplantation, there is every reason to suspect that such a market would create an environment in which ethical abuses are likely to occur. Permitting a market in organs would, contrary to the claims who favor such a system, increase rather than decrease frictions between doctors and their patients.

Traditionally medical ethics in America has required physicians to honor the principle of Do No Harm in treating their patients. This principle enjoins physicians or other health professionals from undertaking procedures or interventions that are not in the patient's best interest. It is difficult to overestimate the critical role this moral rule plays in cementing the physician-patient trust.

Patients simply will not trust their doctors unless they believe that the doctor has their best interest firmly in mind in making recommendations or undertaking care. Trust is essential to the practice of medicine. Patients who do not trust doctors will not seek their care or if they do may not be forthright and open with their them. Such distrust, if it is allowed as a matter of public policy to enter into medicine would have a catastrophic chilling effect on medical care.

Yet this chilling effect is precisely what a market in organs would produce. Could the public really give its trust to a profession whose members are willing to conduct surgery upon patients, not for their benefit, but for the profits that will accrue to the patient and the doctor? Recent public outrage over the overutilization of such surgical procedures as hysterectomies, tonsillectomies and coronary bypass surgery indicates the depth of public concern about this matter. To allow doctors to undertake major risky surgical operations on living donors for the reason of profit and profit alone is to condone a practice which would totally undermine public trust in the medical profession, would violate the existing canons of the ethics of the profession, and, would in all likelihood lead to further abuses of vulnerable patients particularly with respect to experimental transplant procedures.

Health care is a practice that requires its members to adhere to rigorous moral standards and society to recognize and encourage the faithful adherence to these standards if it is to be successful. The provision of life-saving medical services is simply not ethically akin to the provision of beer, tin cans, or airline travel--sectors of the economy where markets can and do work well. Morally responsible societies cannot tolerate the allocation of life saving medical skills solely on the basis of a patient's ability to pay and ours does not as the existence of Medicare and Medicaid prove. Our society should not tolerate a health care system in which doctors decide whether to utilize their services solely from considerations of personal profit rather than in order to help their patients. Patients will not long trust a system in which physicians who have direct financial reasons to down play the various risks of surgery in order to turn a profit by procuring an organ from a living donor are encouraged to do so as a matter of public policy.

Nor is their any reason to assume that a market in organs would help produce a higher quality of organs for transplantation than a voluntary system. The nation's experience with commercial markets in blood has failed to show that donated blood differs in quality from bought blood. Indeed the rather incomplete evidence that is available seems to point in just the opposite direction.

Sperm banks are publicly airing their concern that some of those who are paid for donations may conceal important medical facts about their medical or genetic history. Plasmapheresis centers, who are the major purchasers of blood, are now enormously concerned about the incentives payment gives to donors to conceal facts about their sexual practices--practices which may be implicated in the transmission of various viral diseases through blood transfusions. Concerns for maximizing the quality of the organs available for transplantation from either living or cadaver donors should make us err on the side of banning rather than encouraging the sale of organs.

My most important ethical reservations about permitting the sale of solid organs have nothing to do with matters of supply, quality or trust between doctors and their patients. If our society decides to permit a market in organs it is clear who the majority of sellers will be. They will be the poor and the needy of both this nation and from other nations. Paying the poor to bear the responsibility for supplying our society with needed organs may provide them with additional sources of income but at a terrible moral cost.

There are simply some practices that might be engaged in for money; i.e., slavery, the selling of the dead, suicide, etc., that a moral society ought not tolerate. While there may exist those who are desperate enough to sell all or parts of their bodies to others for money, it is surely not in their best interest to allow them, much less encourage them, to do so. Surely our society can provide better ways for solving the problems of poverty and unemployment than by permitting persons to sell vital organs or families to parcel out the bodily remains of their loved ones to the highest bidder.

Our society is well aware of the coercive power that money can have over those in desperate need. Indeed existing regulations in the area of human experimentation explicitly forbid the payment of funds beyond reasonable expenses for participation in experiments precisely because we know that the prospect of a large profit can make people take short term risks that are not always in their best long term interests. A market in organs poses the same risk for those who might participate--they may be tempted to overlook their own interests, or, the interests and desires of their loved ones out of desperation, callousness or greed. None of these emotions would seem to constitute a solid foundation for public policy with respect to transplantation.

A market in organs may not solve the current shortage in supply and i[illegible] worsen the problem. Permitting a market would surely undermine the public's trust in the medical profession and would jeopardize the ability of physicians to adhere to their long-standing committment to intervene only in the interest of their patient's welfare. Commercial markets would not increase and might lower the quality of organs available for transplant. Finally the sale of organs would encourage those who are the most weak and vulnerable in our society to treat themselves as commodities in the name of short term profit. For pragmatic as well as ethical reasons I believe that Congress should enact H.R. 4080 and prohibit the sale of solid human organs for the purposes of transplantation.

Mr. **Gore**. Thank you very much. I appreciate that statement.

This will be the last interruption. I want to apologize again, Dr. Gorovitz. You have been very patient all day long. We have one more witness. We have a vote on the floor. During these final 2 weeks of the session they schedule very significant bills back-to-back, and we will recess for about 7 or 8 minutes, and then we will conclude the hearing with Dr. Gorovitz' testimony and then have a few questions.

[Recess.]

Mr. **Gore**. The subcommittee will come back to order.

Our final witness today is Dr. Samuel Gorovitz, chairman of the department of philosophy at the University of Maryland. We want to welcome you, Doctor. Thank you for your patience, and please proceed.

Dr. **Gorovitz**. Thank you.

In the interest of accuracy of the record, I point out that I stopped chairing the department about a year and a half ago but I am still in it.

Mr. **Gore**. Well, I am sorry for the error.

Dr. **Gorovitz**. That is all right.

In the interest of time, I will excerpt from the prepared testimony and get through it as quickly as I can.

We are faced with choices which, in the words of Richard Titmus, "* * * lead us, if we are to understand these transactions in the context of any society, to the fundamentals of social and economic life." The question of how to close the gap between the demand for, and the supply of, transplantable organs is no less than the question of what sort of society we wish to advocate, endorse, and nurture.

The Government has a responsibility to step in only where it must, to safeguard the public interest. Further, the Government should exercise great caution in enacting prohibitions on behavior. Only where it can sustain a persuasive justification may it properly constrain the behavior of citizens. It has no business prohibiting actions merely because they are offensive to the sensibilities of a portion of the citizenry or because they could conceivably lead to more serious abuses in the future.

For this reason, I argued before you last year that the appropriate role for the Government in respect to the shortage of organs is catalytic rather than coercive. To require the donation of cadaver organs would be to ride roughshod over the rights of individuals to exercise discretion over the disposition of their bodily remains.

Even to presume consent in the absence of dissent would be to place the burden where it does not belong. Those who prefer not to donate organs for reasons of religion, superstition, or squeamishness, or for no reason at all, would be cast into a defensive position in which they might feel hard pressed to protect themselves and their families against intrusions of a most intimate sort.

Yet, the problem remains and grows, so something must be done. An ideal solution would be a massive shift in national sentiment about transplantation, a shift that would greatly increase participation in donation plans and also reduce the barriers—psychological and economic—to participation by the medical profession in efficient collection and distribution of organs. But ideal solutions are elusive. It is prudent to ask whether we can even approximate to them in fact.

With respect to organ transplantation, we don't yet know the answer to that question. The large shortage of organs is too recent and our current modes of response to that shortage are too unsystematic for us to know what we can yet achieve in the way of an enlightened, collective response. It is time to put that question to the test.

The new American Council on Transplantation may become an effective instrument for rationalizing our methods of collecting and distributing organs and of increasing public participation in donation plans. But that will require it to have significant financial and institutional backing, a firm and energetic resolve, and a fair bit of good luck.

Its prospects of success will be greatly enhanced by H.R. 4080, which, without being coercive or intrusive, fosters a major increase in our structural capacity to achieve an adequate solution based on a voluntary and altruistic response to the plight of potential recipients.

I would just add one word of endorsement of Dr. Veatch's remarks about the composition of the council. I am otherwise enthusiastic about the bill.

This approach must be given every reasonable chance of success, for the alternatives are grim. The demand for transplantation will continue to increase, as will the varieties of transplantable tissues. Today, we focus mainly on kidneys, corneas and livers, knowing that lungs and hearts are also transplantable. But skin, bone, and muscle are transplantable, too, and recent successes in the reattachment of digits and limbs foreshadow the transplantation of those parts in response to major trauma. It would be naive not to realize that we are at the beginning of the problems associated with our newly developed capacities of medical and surgical intervention.

What are those grim alternatives? One of the worst would be a governmental takeover of the whole domain. The disadvantages of that scheme, I trust, need no elaboration here.

Another alternative—and our focus today—is the commercial market. Despite all we have heard, I think the disadvantages of that scheme invite a bit of further elaboration. Dr. Jacobs has proposed to commission the sale of kidneys from persons, initially in the Third World, for whatever price is needed to induce them to sell, and then to broker them to affluent Americans. The brokerage fees will make the enterprise, in his own words, "a very lucrative business".

This plan raises many questions beyond the immediate need for more kidneys. A frequent initial response to the Jacobs scheme is that it is morally repugnant. But so might an appendectomy be to one who is innocent of the benefits of abdominal surgery. Is the distaste engendered by Jacobs' scheme not also a result of a shallow reaction, prompted by an unfamiliar solution to a new but vital problem? That, at least, is what he would have us believe.

He defends his scheme with a veneer of humanitarianism, public service, and the American way. Before we legislate him out of business, we had best consider the merits of his case. For it is not simply a question of the economic ambitions of one ex-practitioner from Virginia. It is a question of determining important features of the distribution of vital resources for the challenging years to come.

People beset by extreme poverty, malnutrition, and ignorance live in desperate circumstances. So do those with end-stage renal failure. Surely, one aspect of Jacobs' plan is that it is profiteering on the desperation of these two groups. But if, as he claims, all related transactions are to proceed by the voluntary actions of fully informed and uncoerced adults, we must pause before concluding that there is a legitimate public interest in prohibiting these exchanges.

At least, as Jacobs claims, his plan will deliver kidneys to people who need them and cash to people who need it, possibly to their mutual benefit. And with the traditionally admirable flexibility of the free market system, the scheme can function long before the catalytic efforts of the Government or the American Council on Transplantation can take effect.

Many assumptions in Jacobs' scheme are open to challenge. The risks to donors are greater than he has admitted. The scheme makes a mockery of informed consent, as is evident to anyone familiar with Federal regulations protecting human research subjects—which reflect a sensitive awareness that desperate circumstances can be implicitly coercive, and that the provision of excessive inducements to the oppressed can constitute a violation of their autonomy. And there are problems of quality control that might be insuperable.

But I think we miss the most fundamentally important issues if we focus on such weaknesses in the proposal. Larger matters are at stake.

There are various standards for judging the greatness of a society: By the peaks of its achievements in the arts and culture or in technology, by the average material standard of living of its people, by the scope of its territorial authority, and so on.

I have always thought one appropriate standard for judging the greatness of a society is that of how it treats those whom it treats least well. The analog at the level of the family is compelling, at least.

No matter how we admire the talented, affluent, accomplished family next door, our judgment of them would plummet if we discovered they had one family member whom they abused, whose interests they ignored, whose needs left them unmoved, whom they exploited to their own maximum advantage. Such a discovery would provide us with important information about their character and integrity, about their sense of connectedness to one another, and their sense of justice within a social structure.

Judged by the analogous criterion, American society does not yet live up to its loftiest ideals.

Another criterion for judging the greatness of a society—related to but different, a little bit, from the previous one—is the way it treats its most seriously disadvantaged. People in grinding poverty and those beset by life-threatening illness are surely in highly disadvantaged circumstances. What societal response to their plight do we wish to endorse?

A free market model is based on the values of competition, individual initiative, and the elasticity of supply and demand in response to market forces. But medical need is no respecter of success in the world of commerce. The poor are more likely, not less, to be seriously ill, and their ability to obtain medical care is seriously compromised by their poverty.

To distribute vital resources according to ability to pay is to set aside all concern for medical needs as the primary determinant of access. It is to set aside considerations of compassion and cooperation, and abandon the effort to fashion a society in which mutual supportiveness is our response to desperation. It is to sanction the expansion of unfettered commercialism into dimensions of life which could just possibly provide us the opportunity to achieve a greater sense of community and national purpose than we have previously known, except in the face of external threat. It is to ask far too little of ourselves.

The argument for a commercial market in kidneys might have greater force had we put ourselves to the test and failed. But we are just now acknowledging a new national need. H.R. 4080 seeks to fashion a constructive response to that need. It is far too soon to judge that response a failure. It is too soon even to decide, as we may be able to decide in a year, whether that response has been able to match the sizzling pace of new medical developments.

The only adequate barrier to the commercialization of life is a new legislative prohibition. Such a prohibition is necessary to put to the test our capacity as a Nation to meet the present shortage and to fashion ways to deal with future shortages with a due respect for equality and social justice.

We are well-advised to temper our passionate and worthy defense of liberty with a due consideration of the social context without which our liberty would be a tragically empty achievement.

An additional reason for supporting the prohibition derives from the symbolic significance of the proposed market in organs. At a time when we urgently need to nurture good relations with the Third World, our international credibility would be dealt a severe blow by our tolerance of a plan according to which the poor in underdeveloped countries were exploited as a source of spare parts for rich Americans. Our antagonists behind the Iron Curtain would love such a public relations windfall, and they would be right.

In the Third World, it is unlikely that strong restrictive action will effectively prevent the plundering of peasants' parts for profit. Their public health concerns are still centered on problems of sanitation, nutrition and infectious disease. If there are to be effective controls, they must be at our end. But it is no surprise, nor inappropriate, that the world's most highly developed nation should bear the burdens of exercising responsibility over medical science's most advanced capacities.

Nor should we be swayed by the claim that commercial markets in live organs will develop elsewhere no matter what we do, and that wealthy Americans will be the recipients anyway. Whether that is so remains to be seen, but has no bearing on the fact that we must act rightly as we can best judge the right. If we want the world to be inspired and informed by our example as a humane and just society, we must be prepared to provide that example.

I am not concerned merely with the prospects for international exploitation, and the damage that threatens for our image abroad. I pressed Barry Jacobs in debate to explain why he prefers to seek organs elsewhere—before his latest version of the scheme—rather than from among America's downtrodden—the street people in New York, the unemployed migratory farmworkers, the innercity destitute, the most impoverished of native Americans. He then replied that he will go abroad for kidneys only if American sources are inadequate to meet the demand. Thus would he have us turn on our own poor to seek relief for our well-to-do.

I am concerned, of course, with what such markets would do to those whose destitution and desperation might move them to sell bodily parts in the hope of gaining a foothold for the climb out of poverty. But I am concerned even more about what such behavior would do to the rest of us, and what it would reveal about our compassion and our commitment to equality, our willingness to face common problems with collective resolve, our capacity to make voluntary efforts in the public interest, and more.

That the poor are exploited is unarguable. That their poverty seems intractable is a continuing tragedy of our unprecedentedly affluent society. I hope that history will be able to judge us as a society that never abandoned its struggle to eliminate that poverty, that strove ever to enhance and enrich its respect both for individuals and for their capacity for mutual aid, and that faced the problems of an awesome new technology with humanity and efficiency both, rather than as merely another commercial opportunity. I believe there is a legitimate public interest in striving to bring that about.

Thank you.

[The prepared statement of Dr. Gorovitz follows:]

TESTIMONY: HOUSE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

Samuel Gorovitz

Congessman Gore and Members of the Subcommittee, I welcome the opportunity to discuss with you some of the problems associated with recent developments in transplant surgery. I take it that these facts, at least, are uncontroversial: that there has been a sharp, recent increase in our capacity to transfer living tissues of various kinds successfully from donors to recipients, that there is in consequence a large and growing shortage of transplantable materials, and that controversial economic, political, and moral issues swirl around our efforts to respond to this new situation.

How can we best meet the vital needs of patients who require transplant surgery, while respecting the various related interests and concerns which come into play? We are faced here with choices which, in the words of Richard Titmus, "lead us, if we are to understand these transactions in the context of any society, to the fundamentals of social and economic life." The question of how to close the gap between the demand for and the supply of transplantable organs is no less than the question of what sort of society we wish to advocate, endorse, and nurture.

The range of possible responses is great. We have heard proposals to presume consent by prospective donors in the absence of clear evidence to the contrary, proposals to establish commercial markets in organs, and proposals to increase the efficiency of present approaches through devices ranging from tax incentives to public education. I am not aware that anyone has yet proposed seriously that transplantable organs should be made available without regard to the wishes of the person whose organs are at issue -- but such a proposal would not surprise me.

The focus of this testimony is the specific question: what should the government do, promote, permit, or prohibit in respect to organ transplantation? Any response to that question must rely on a broader conception of the proper role of government generally. So I want to be clear at the outset about some of my convictions in that regard.

It is not the responsibility of government to be the solution of first resort to the problems of contemporary society; rather, the private sector is our best hope for meeting a broad range of needs. The government has a responsibility to step in only where it must, to safeguard the public interest. Further, the government should exercise great caution in enacting prohibitions on behavior. Only where it can sustain a persuasive justification may it properly constrain the behavior of citizens; it has no business prohibiting actions merely because they are offensive to the sensibilities of a portion of the citizenry, or because they could conceivably lead to more serious abuses in the future. Nor may it require actions simply because they would be in the public interest. Requiring actions (such as the payment of taxes or participation in national defense in wartime) or prohibiting actions (such as violation of the civil liberties of citizens) requires strong justification indeed.

It is for this reason that I argued before you last year that the appropriate role for the government in respect to the shortage of organs is catalytic rather than coercive. To require the donation of cadaver organs would be to ride roughshod over the rights of individuals to exercize discretion over the disposition of their bodily parts. Even to presume consent in the absence of dissent would be to place the burden where it does not belong. Those who prefer not to donate organs, for reasons of religion, superstition, or squeamishness, or for no reason at all, would be cast into a defensive position in which they might feel hard pressed to protect themselves and their families against intrusions of a most intimate sort.

Yet the problem remains and grows, so something must be done. An ideal solution would be a massive shift in national sentiment about transplantation -- a shift that would greatly increase participation in donation plans, and would also greatly diminish the barriers, psychological and economic, to participation by the medical profession in efficient collection and distribution of organs.

Ideal solutions are always elusive, and it is prudent to ask whether we can even approximate to them in fact. With respect to organ transplantation, we do not yet know the answer to that question. The large shortage of organs is too recent, and our current modes of response to that shortage are too unsystematic, for us to know what we can yet achieve in the way of an enlightened collective response.

It is time now to put that question to the test. The newly created American Council on Transplantation may become an effective instrument for rationalizing our methods of collecting and distributing organs and of increasing public participation in donation plans -- but that will require it to have significant financial and institutional backing, a firm and energetic resolve to meet its objectives, and a fair bit of good luck. Its prospects of success will be greatly enhanced by the passage of HR4080, which, without being coercive or intrusive, fosters a major increase in our structural capacity to achieve an adequate solution based on a voluntary and altrustic response to the plight of potential transplant recipients.

Such an approach must be given every reasonable chance of success, for the alternatives are grim. The demand for transplantation will continue to increase, as will the variety of transplantable tissues. Today, we focus mainly on kidneys, corneas, and livers, knowing that lungs and hearts are also transplantable. But skin, bone, and muscle are transplantable, too, and recent successes in the reattachment of digits and limbs foreshadow the transplantation of such parts in response to major trauma. It would be naive not to realize that we are at the beginning of the problems associated with our newly developed capacities of medical and surgical intervention.

And what are those grim alternatives? One of the worst would be a governmental take-over of the whole domain, responding to national shortages with national systems of allocation in accordance with national criteria, supported by mandatory and intrusive processes of collection. The disadvantages of such a scheme, I trust, need no elaboration here. However, a comparable peril exists on the other side. For, another alternative to the present shortage is to allow a commercial market to flourish, linking supply and demand through the mechanisms of free-enterprise. And the disadvantages of that scheme do require some elaboration.

Already, H. Barry Jacobs of Virginia has established a business for the commercial brokering of kidneys. As you doubtless know, he has proposed to commission the sale of kidneys from persons, initially in the Third World, for whatever price is needed to induce them to sell, and then to broker the kidneys to affluent Americans who need transplantable organs and can meet the costs. The brokerage fees will make the enterprise, in Jacobs' own words, "a very lucrative business."

It is important to think carefully about this plan, more deeply than at a level of initial reactions. For it raises many questions that go beyond the immediate need for more kidneys. A frequent initial response to the Jacobs scheme is that it is morally repugnant. But so might an appendectomy be to one who is innocent of the benefits of abdominal surgery. Is the distaste engendered by Jacobs' scheme not also a result of a shallow reaction, prompted by an unfamiliar solution to a new but vital problem? That, at least, is what he would have us believe; he defends his scheme with a veneer of humanitarianism, public service, and the American way. Before we legislate him out of business, we had best consider the merits of his case. For it is not simply a question of the economic ambitions of one ex-practitioner from Virginia; it is a question of determining important features of the distribution of vital resources for the challenging years to come.

People beset by extreme poverty, malnutrition, and ignorance live in desperate circumstances. So, too, do those with end-stage renal failure. Surely one aspect of the Jacobs scheme is that it is profiteering on the desperation of these two groups. But if, as he claims, all related transactions are to proceed by the voluntary actions of fully informed and uncoerced adults, we must pause before concluding that there is a legitimate public interest in prohibiting such exchanges. At least, as Jacobs points out, his plan will deliver kidneys to people who need them, and cash to people who need it, possibly to their mutual benefit. And with the traditionally admirable flexibility of the free-market system, the scheme can function, long before the catalytic efforts of the government or the American Council on Transplantation can take effect.

Many assumptions in the Jacobs scheme are open to challenge. The risks to donors are greater than he has admitted, for example. And the scheme makes a mockery of informed consent, as is evident to anyone familiar with Federal regulations protecting human research subjects, which reflect a sensitive awareness that desperate circumstances can be implicitly coercive, and that the provision of excessive inducements to the oppressed can constitute a violation of their autonomy. And there are problems of quality control that might be insuperable.

But we miss the most fundamentally important issues, if we focus our attention on such weaknesses in the proposal that there be a commercial market in kidneys. Very much larger matters are at stake.

There are various standards for judging the greatness of a society. One measure is by the peaks of its achievements in the arts and culture, or in technology. Another measure is the average material standard of living of its people. A third is the scope of its territorial authority. And so on.

I have always thought that one appropriate standard for judging the greatness of a society is that of how it treats those whom it treats least well. The analogue at the level of the family is compelling, at least. No matter how we admired the talented, affluent, accomplished family next door, our judgment of them would plummet if we discovered that they had one family member whom they abused, whose interests they ignored, whose needs left them unmoved, and whom they exploited to their own maximum advantage. Such a discovery would provide us with important information about their character and integrity -- about their sense of connectedness to one another and their sense of justice within a social structure. Judged by the analogous criterion, American society does not yet live up to its loftiest ideals.

Another criterion for judging the greatness of a society is the way it treats its most seriously disadvantaged. (This criterion is related to, but is not the same as, the previous one.) People in grinding poverty and those beset by life-threatening illness are surely in highly disadvantaged circumstances. What societal response to their plight do we wish to endorse?

A free market model is based on the values of competition, individual initiative, and the elasticity of supply and demand in response to market forces. But medical need is no respector of success in the world of commerce. The poor are more likely, not less likely, to be seriously ill, and their ability to obtain medical care is seriously compromised by their poverty. To distribute vital resources according to abilty to pay is to set aside all concern for medical need as the primary determinant of access. It is to set aside considerations of compassion and cooperation, and abandon the effort to fashion a society in which mutual supportiveness is our response to desperation. It is to sanction the expansion of unfettered commercialism into dimensions of life which could just possibly provide us the opportunity to achieve a greater sense of community and of national purpose than we have previously known, except in the face of external threat. It is to ask far too little of ourselves.

The argument for a commercial market in kidneys might have greater force had we put ourselves to the test, and failed. But we are just now acknowledging a new national need, and HR4080 seeks to fashion a constructive response to that need. It is far too soon to judge that response a failure; it is too soon even to decide, as we may be able to decide a year from now, whether that response has been able to match the sizzling pace of new medical developments.

The only adequate barrier to the commercialization of life as proposed by Jacobs is a new legislative prohibition. I support that prohibition for many reasons, and I do so as one reluctant to endorse any unnecessary restriction on individual liberty. Such a prohibition, however, is necessary to put to the test our capacity as a nation to meet the present shortage, and to fashion ways to deal with future shortages, with a due respect for the dictates of equality and social justice. The credo of the French revolution -- liberty, equality, and fraternity -- can remind us at times like this that we are well advised to temper our passionate and worthy defense of liberty with a due consideration of the social context without which our liberty would be a tragically empty achievement.

An additional reason for supporting the prohibition derives from the symbolic significance of the proposed market in organs. At a time when we urgently need to nurture good relations with the nations of the third world, our international credibility would be dealt a severe blow by our tolerance of a plan according to which the poor in underdeveloped countries were exploited as a source of spare parts for rich Americans. Our antagonists behind the iron curtain would love such a public relations windfall -- and they would be right.

In the third world, it is unlikely that strong restrictive action will effectively prevent the plundering of peasants' parts for profit. Their public health concerns are still centered on problems of sanitation, nutrition, and infectious disease. If there are to be effective controls, they must be at our end. But it is no surprise, nor inappropriate, that the world's most highly developed nation should bear the burdens of exercizing responsibility over medical science's most advanced capacities.

Nor should we be swayed by the claim that commercial markets in live organs will develop elsewhere no matter what we do, and that wealthy Americans will be the recipients in any case. Whether or not that is so remains to be seen, but has no bearing on the fact that we must act rightly as we can best judge the right. If we want the world to be inspired and informed by our example as a humane and just society, we must be prepared to provide that example.

I am not concerned merely with the prospects for international exploitation, and the damage that threatens for our image abroad. I have pressed Barry Jacobs in debate to explain why he prefers to seek organs elsewhere, rather than from among America's downtrodden -- the street people in New York, the unemployed migratory farm laborer, the inner city destitute, the most impoverished of our Native Americans on reservations. And he has replied that he will go abroad for kidneys only if these American sources are inadequate to meet the demand. Thus would he have us turn on our own poor to seek relief for our well-to-do.

I am concerned, of course, with what such markets would do to those whose destitution and desperation might move them to sell bodily parts in the hope of gaining a foothold for the climb out of poverty. But I am concerned even more about what such behavior would do to the rest of us, and what it would reveal about our compassion, our commitment to equality, our willingness to face common problems with collective resolve, our capacity to make voluntary efforts in the public interest, and more.

That the poor are exploited is unarguable. That their poverty seems intractible is a continuing tragedy of our unprecedentedly affluent society. I hope that history will be able to judge us as a society that never abandoned its struggle to eliminate that poverty, that strove ever to enhance and enrich its respect both for individuals and for their capacity for mutual aid, and that faced the problems of an awesome new technology with humanity and efficiency both, rather than as merely another commercial opportunity. I believe there is a legitimate public interest in striving to bring this about.

Mr. **Gore**. Thank you. That was well worth waiting for. I appreciate such a powerful and eloquent statement.

I take it that there is unanimity on this panel that buying and selling human organs would be a bad idea, on balance?

Dr. Brenner, the implications of the statement you presented I think obviously bear further scrutiny. We cannot do that in detail here, but your conclusion is that, at the present time, your findings are not sufficient to lead you to advise against living-related donations, but they do lead you to believe there should be greater care, and certainly more scrutiny, in order to determine whether these results are, as you put it, the tip of an iceberg or not.

Certainly they challenge any assumption that the risks of organ donation by a living donor are far from negligible. They are somewhere between negligible and prohibitory, but they may be more significant than we have assumed in the past. Is that a fair summary?

Dr. **Brenner**. Very fair.

Mr. **Gore**. OK. Since we have had such a long day, I am not going to prolong the hearing with a lot of questions. I think that your statements are all very eloquent, and I appreciate the obvious time and effort that you have put into them.

I, too, believe that there are larger questions involved here. We do have to decide what kind of society we are going to become. We are experiencing a pace of change unprecedented in all of human history. The recent advances in organ transplantation serve as only one small example of how advances in science and technology are challenging the ethical and legal underpinnings of our civilization.

If we are going to adapt well, we're going to have to engage in a lot of discussions like the one we have had here today, and we are going to have to make some hard choices, like the ones posed by Dr. Jacobs' plan.

I think that H.R. 4080 makes the correct choice with regard to the buying and selling of human organs. I am comforted by the fact that a panel as distinguished as this one supports that judgment.

I do not believe it is a completely open-and-shut case, and I understand that you all appreciate the subtleties involved in these ethical judgments. But I think, on balance, the answer is a fairly decisive one. Again, I am comforted by the fact that you agree.

Let me thank you all again for your testimony here and for your assistance in our exploration of this issue. We are going to continue as a subcommittee to try to improve the way our country deals with organ transplantation, and your contribution today has been extremely significant.

Thank you very much.

[Whereupon, at 2:20 p.m. the subcommittee was adjourned.]

APPENDIX

HOWARD UNIVERSITY HOSPITAL
2041 GEORGIA AVENUE, N.W.
WASHINGTON, D.C. 20060

November 18, 1983

Representative Albert Gore, Jr.
Chairman, Sub-Committee on Investigations and Oversight
U.S. House of Representative
Committee on Science and Technology
Suite 2321 Rayburn House Office Building
Washington, D.C. 20512

Dear Representative Gore:

Thank you for your letter of October 25, 1983 and an opportunity to testify before your committee. The following answers are in response to your queries:

The Howard University Transplant Center is a predominately black transplant center having performed more than 150 kidney transplants since July 1974, we place no emphasis on histocompatibility regarding cadaver organ transplantation; but rather emphasize clinical factors and a negative leukocyte cross match to determine whether an organ should be transplanted or not.

Fifteen, nineteen and twenty-two kidney transplants were performed by us in 1981, 1982 and 1983 respectively. During this time interval no non-resident alien transplants were performed.

There has been only one non-resident alien transplanted at our institution since 1974. This patient was referred to us by his older brother, who was a physician at another local hospital. This patient's first transplant was from a living related donor. The second was a cadaver transplant which was handled as a teaching case because the family did not have the funds to pay for the services.

The policy statement on kidney transplantation on non-immigrant aliens of the End Stage Renal Disease Network and the Howard University Hospital Transplant Centers reads as follows:

> Within the geographic area of the End Stage Renal Disease Network of the Greater Capital Area, Inc., transplantation of both residents and "non-immigrant aliens" (the legal

> terminology for people who are temporarily in this country specifically for medical care) has increased during the last several years. The Medical Review Board of the Network felt that residents might be at a disadvantage in waiting for a cadaveric kidney transplant because they were competing with non-immigrant aliens for cadaveric organs on the SEOPF computerized waiting list. Residents in general were thought to be listed for more extensive tissue typing matches to minimize the probability of rejection and consequently were waiting for longer periods of time. Because the cost of the End Stage Renal Disease Program, including organ procurement activities, is underwritten by the Medicare Program, the Medical Review Board felt that the policy should be adopted so that U.S. residents would not be disadvantaged in waiting for a cadaveric kidney.
>
> When making decisions regarding the placement and receipt of cadaveric kidneys, the organ procurement coordinators at each Network 23 transplant program should search by preference for a compatible recipient who is a U.S. resident. This search should include the harvesting institution itself and Washington area transplant hospitals, as well as a review of regional and UNOS (United Network of Organ Sharing) computer listings, unless the characteristics of the kidney require prompt placement. For this purpose, non-immigrant aliens should be identified in each transplant program.

The Howard University Hospital Transplant Center does not have any form of agreement with any foreign governments. The institution does not have any non resident aliens who are on dialysis or who are potential transplant recipients. It has been the history of our unit to only see the non resident aliens that do not have the ability to pay for services.

Our policy on shipping organs out of the country is that organs are shipped after an exhaustive search has been made locally, regionally and nationally and there were no acceptable recipients. Our institution has shipped only one pair of kidneys out of the country they were AB kidneys with no recipients available in the U.S. Blood Type AB kidney recipients generally are a very small pool of patients. This set of kidneys were, therefore, sent to Japan.

Letter to Representative Gore
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November 18, 1983

I hope my testimony will make a valuable contribution to your subcommittee's effort, and if any questions remain, please feel free to contact me.

Yours truly,

Clive O. Callender, M.D.

Clive O. Callender, M.D., F.A.C.S.
Professor and Vice-Chairman
  Department of Surgery
Director, Howard University
  Transplant Center

COC/tw

H. BARRY JACOBS, M.D.
Diplomate of the American Board of Surgery
Diplomate of the National Board of Medical Examiners
Medical Director

TOLL FREE 800-336-0332
DC and VA (703) 435-9400

International Kidney Exchange, Ltd.
11345 Sunset Hills Road
Reston, Virginia 22090 U.S.A.

November 9, 1983

Albert Gore, Jr.
Chairman
Subcommittee on Investigation and Oversight
U.S. House of Representatives
Suite 2321
Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Gore:

Thank you for inviting me to testify before your committee today. I want to clarify five specific points and have this letter made a part of my official testimony for the record.

There are five specific methods and sources for obtaining kidneys which I will discuss briefly below.

1. The voluntary cadaver system. This is the current program in which only ten percent of brain dead respirator-supported patients have had their organs retrieved for transplantation. This requires immediate permission from the next of kin. This program has been a failure, and I don't think further education of the public will make any meaningful increase in that source, but I hope it does.

2. The monetary cadaver system. Here the government could encourage next of kin to allow their brain dead relative's organs to be retrieved and equitably distributed to those currently waiting for cadaver organs. This will not be a private venture. I believe this will substantially increase the supply.

3. Monetary system for individuals to sign up now so should they become one of the unfortunate twenty-two thousand brain dead Americans on respirators, their organs can be retrieved. This is a "living will", a type of "organ insurance". This will substantially increase the supply, and of course not interfere with the existing program in number one above. It would only augment it, and be run like the government program proposed in paragraph two above. This should solve the entire problem of organ shortages.

Congressman Gore
November 9, 1983
Page Two

4. Living related donors. This is an existing system. There is potential for psychological injury for those who refuse to cooperate, as well as those who do cooperate but have their kidney rejected in the body of their loved one. This option would always be available to augment the above programs.

5. Unrelated living donors compensated for their donation of a kidney. The physicial risk is the same as that of a living related donor. The psychological risk is much less and of course the same stringent psychological and physicial examination criteria, as well as matching criteria, must be maintained. This is a program which currently is necessary to augment the dismal failure of the voluntary cadaver system. Should other programs above meet the need, the marketplace will eliminate this option. The marketplace, not Congress, and not anti-trust actions by the transplant surgeons groups, should dominate in our American system. As I pointed out, this is not Russia where the government owns your organs at the time of death, and you are proposing a system where the government controls a healthy adult's consenting decision to give up one of their healthy kidneys. You also want to legislate medical ethics and interfere with the doctor-patient relationship.

Furthermore, the unrelated living donor program would be an immediate way to end the dehumanizing misery of many of the 70,000 Americans and at the same time save our government, our taxpayers, and your constituency, billions of dollars every year, year after year.

Sincerely yours,

H. Barry Jacobs, MD

H. Barry Jacobs, M.D.
Medical Director

HBJ/fca